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Editorial

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Bisphosphonates and atypical femur fractures

Nasseer A Masoodi

Bisphosphonates, which have been on the market for roughly a decade, have raised safety concerns in the past. Several case series and multiple individual case reports suggest that some subtrochanteric and femoral shaft fractures may occur in patients who have been treated with long-term bisphosphonates. Several unique clinical and radiographic features are emerging. Recent media spotlight in the United States (US), implying that long-term use of alendronate could cause spontaneous femur fractures in some women, has reignited the debate about the safety of bisphosphonates. *The question posed: is the risk of bisphosphonate-associated fractures so great that treatment should be stopped?*

Postmenopausal women with osteoporosis are commonly treated with the bisphosphonate class of medications, one of the most frequently prescribed medications in the US. While alendronate therapy has been shown to decrease the risk of vertebral and femoral neck fractures in postmenopausal osteoporotic patients, recent reports have associated long-term alendronate therapy with low-energy subtrochanteric and diaphyseal femoral fractures in a number of patients. In the past four years reports have been published implying that long-term bisphosphonate therapy could be linked to atraumatic femoral diaphyseal fractures.[1, 2] According to two studies reported recently at the American Association of Orthopedic Surgeons 2010 Annual Meeting, an unusual type of bone fracture has been reported in women who have taken bisphosphonates for osteopenia and osteoporosis for more than four years.[3, 4] The first report was published in 2005. Odvina et al[5] reported on nine patients who sustained atypical fractures, including some with delayed healing, while receiving alendronate therapy. These authors raised the concern that long-term bisphosphonate therapy may lead to over-suppression of bone remodelling, an impaired ability to repair skeletal microfractures, and increased skeletal fragility. There have been other reports of "peculiar" fractures - i.e. low-energy femur fractures that are typically transverse or slightly oblique, diaphyseal, or subtrochanteric, with thickened cortices and a unicortical beak - in patients who have been on long-term bisphosphonate treatment.[1-4, 6]

In a small prospective study, Lane et al[3] obtained bone biopsies from the lateral femurs of 21 postmenopausal women with femoral fractures. Twelve of the women had been on bisphosphonate therapy for an average duration of 8.5 years, and nine had no history of bisphosphonate use. They found that the heterogeneities of the mineral/matrix ratio were significantly reduced in the bisphosphonate group by 28%, and the crystallinity of the bone was significantly reduced by 33% ($p < 0.05$). The authors concluded that this suggested suppression of bone turnover, resulting in a loss of heterogeneity of the tissue properties, which may be a contributing factor to the risk of atypical fractures that we are starting to see. It is believed that long-term alendronate administration may inhibit normal repair of microdamage arising from severe suppression of bone turnover (SSBT), which, in turn, results in accumulation of microdamage. This process would lead to brittle bone and the occurrence of unexpected stress fractures, characteristically at the subtrochanter of femur. The typical presentation of these fractures consist of prodromal pain in the affected leg and/or a discrete cortical thickening on the lateral side of the femur in conventional radiological examination or the presentation with a spontaneous transverse subtrochanteric femur with typical features. The morbidity of atypical femoral fractures, particularly when bilateral, is high. Surgical intervention is generally required and healing may not be achieved for several years. Despite the lack of conclusive evidence of a causal relationship with bisphosphonate therapy, the current consensus is that treatment should be discontinued in patients who develop these fractures. In view of the high frequency of bilateral involvement, imaging of the contralateral femoral shaft with X-rays, MRI, or an isotope bone scan should be performed. MRI and bone scanning havegreater sensitivity than radiography for an incipient stressfracture. If lateral cortical thickening and/or an incipient stress fracture is seen, prophylactic surgical fixation should be considered. Suppressed bone formation in these patients provides a possible rationale for the use of anabolic skeletal agents, such as parathyroid hormone peptides, but at the present time the efficacy of this approach remains to be established. Parathyroid hormone not only has activated bone-formation markersin trials in humans but has also enhanced the healing of fracturesin studies in animals.

The question of whether these fractures are causally linked to bisphosphonate therapy is widely debated but as yet unresolved. Consequences of long-term suppression of bone

turnover include increased mineralization of bone, alterations in the composition of its mineral/matrix composite and increased micro damage, all of which may reduce bone strength. Whilst these lend biological plausibility to a causal association, however, they do not constitute direct evidence. The bilateral fractures seen in many patients corroborate the suspicion that patients with bisphosphonate-associated stress fractures carry some other risk factor in addition to taking the drug. Microfractures,inadequate mineralization, and outdated collagen are some of the candidate causes. However, until further studies can provide definitive evidenceof bisphosphonate-associated fractures, it is premature to attributeatypical fractures to over-suppression of bone turnover alone,while disregarding secondary and patient-related factors. Many experts believe that prolonged suppression of bone remodelling with alendronate may be associated with a new form of insufficiency fracture of the femur. Studies have not shown if the entire class of medications produce a similar result, but patients who have been treated with any bisphosphonate for an extended period of time should be considered at risk.

A wealth of information from well-designed clinical trials clearly shows that, as a class, bisphosphonates are highly effective at limiting the loss of bone mass, deterioration of bone micro architecture, and increased fracture risk that occur with aging. The benefit/risk ratio of bisphosphonate therapy in patients at high risk of fracture remains overwhelmingly positive because of the very low incidence of atypical femoral fractures. Current estimates suggest that alendronate prevents 200 clinical fractures if 4000 women are treated over three years and will cause one femur fracture over the same course of time.[7] A study by Schilcher et al[8] found that the incidence density of a stress fracture for a patient on bisphosphonate was 1/1000 per year (95% CI: 0.3-2), which is acceptable considering that bisphosphonate treatment is likely to reduce the incidence density of any fracture by 15/1000.[9] Nevertheless, limitation of treatment duration to five years in the first instance, with evaluation of the need to continue therapy thereafter, may be appropriate in clinical practice. The Fracture Intervention Trial Long-term Extension (FLEX), in which postmenopausal women who had received alendronate therapy for five years were randomised to continue receiving alendronate for five additional years or switched to placebo, provided clinical evidence that the effect of bisphosphonate therapy was maintained after discontinuation of therapy.[7, 10] Women who are being treated with bisphosphonates should take a drug holiday if they have been on them for five years. Patients in whom bisphosphonate therapy is discontinued should typically follow up with bone mineral density measurements at 1- to 2-year intervals, with some experts advocating periodic measurement of biochemical markers of bone turnover to detect loss of the antiresorptive effect. Additional research is necessary to determine the exact correlation between the use of bisphosphonates and spontaneous or low-energy trauma fractures.

Competing Interests
None declared
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Research Article

BJMP 2010;3(1):303

The Exeter Trauma Stem: Early results of a new cemented Hemiarthroplasy for femoral neck fracture

David Cash , Jens Bayer , Karl Logan and James Wimhurst

ABSTRACT

Introduction: The Exeter Trauma Stem (ETS) is a new monoblock unipolar prosthesis with no independent published series using this implant. This study prospectively evaluates the first 50 ETS hemiarthroplasties performed as a primary treatment for fractured neck of femur at Norfolk and Norwich University Hospital.

Methods: Patient demographics and operative details were recorded from the patient notes. Radiographic evaluation involved the Barrack cementation grading system, Dorr's criteria and leg length measurement. All patients were sent an Oxford Hip Score questionnaire between two and four months postoperatively with 100% response rate.

Results: Two thirds of cement mantles were Barrack grade A and B. Twenty-eight patients had lengthening of the operated limb with a mean of 12mm (5-30) including one irreducible prosthesis. Further complications included three deaths and one deep infection. The average Oxford Hip Score was 27.2.

Discussion: Patient demographics were similar to previous studies. There was no statistical difference between the cement mantles and those of another published study using the Exeter stem. The major difficulty evident from this study was correct positioning of the prosthesis with regards to leg-length. Post-operative hip scores were similar to other studies as was the mortality rate.

Conclusion: Post-operative functional and radiographic scoring of the ETS prosthesis were encouraging but care is needed with regards to correct positioning of this prosthesis to attain equal leg lengths. Subsequent to the results of this study, a trialling system has been added to the instrumentation which the authors recommend in conjunction with pre-operative templating.

KEYWORDS

Exeter Trauma Stem, Cemented hemiarthroplasty, Hip fractures, Leg length inequality, Barrack Grading, Oxford Hip Score.

INTRODUCTION

The Western world is experiencing a rapid increase in the incidence of femoral neck fractures, from 50000 fractures in 1990 to a projected 120000 in 2015[1] as the age of the population increases. Hip fractures account for approximately 20 percent of orthopaedic bed occupancies in Britain at a total cost of up to £25000 per patient[1].Around half of these fractures are intracapsular in nature of which two thirds are displaced.

The ideal surgical treatment for displaced intracapsular femoral neck fractures remains controversial with studies indicating a lack of consensus among treatment centres[2,3]. Options include reduction with internal fixation, cemented or cementless hemi-arthroplasty and total hip replacement. Internal fixation is less traumatic than arthroplasty but has a higher re-operation rate[4,5] whilst cemented femoral prostheses are associated with a lower rate of revision compared to cementless implants. In addition there are statistically significant improvements in pain scores, walking ability, use of walking aids and activities of daily living within the cemented group[6,7]. The cementation process may however be associated with increased morbidity due to fat embolisation and increased length of operation[8].

Treatment planning for intracapsular fractures, therefore, needs to take into account the patient's medical fitness and activity level as well as the cost-effectiveness of the procedure.

Figure 1: Exeter Trauma Stem (ETS) Implant

The Exeter Trauma Stem is a new monoblock unipolar implant using an intermediate size 1.5, forty millimetre offset Exeter stem with a large head sized to match the patient's anatomy (Figure 1, 2).

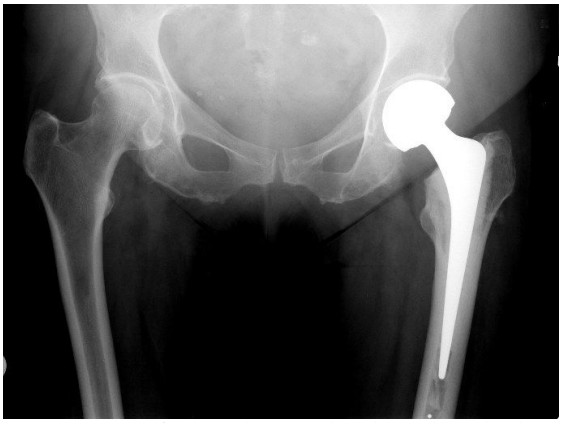

Figure 2: X-ray of ETS with correct length. Neck cut has been made 1cm above lesser trochanter with shoulder of prosthesis sunk below greater trochanter to ensure equal leg length

As yet there are no independent published series of the results of using this implant. Purported advantages of the ETS include the use of a tried and tested polished, tapered stainless steel stem with which many primary hip surgeons are familiar, ease of 'cement-in-cement' revision to a total hip replacement should the patient develop acetabular erosion and the relatively low cost of £240 compared to many contemporary cemented implants.

This study prospectively evaluates the first 50 ETS hemiarthroplasties performed at the Norfolk and Norwich University Hospital, UK over a six month period providing an indication of early outcomes and complications involved with the use of this prosthesis.

METHOD

Patients presenting to our unit with a displaced intracapsular femoral neck fracture who were sufficiently active to get out of their home independently, had an ASA grade of 1 or 2 and were not significantly cognitively impaired were treated with a cemented ETS prosthesis. In addition, patients with displaced intracapsular fractures associated with significant comminution of the medial femoral neck precluding the use of our standard calcar-bearing Austin Moore (Stryker Howmedica Osteonics Ltd) hemiarthroplasty were also treated with an ETS regardless of functional capability and medical condition.

The first fifty patients who underwent ETS hemiarthroplasty as a primary treatment for fractured neck of femur were included in the study. Four patients were excluded. Two of these patients had an ETS performed due to failure of cancellous screw fixation and two as part of a two stage revision for infected uncemented prosthesis.

All fifty procedures were performed with the patient in the lateral position via the modified lateral approach with the glutei incised at the musculotendinous junction. Cefuroxime was given on induction in each instance followed by two post operative doses at eight and sixteen hours after the procedure. Patients were scored by the hospital protocol for risk of thrombosis and were administered aspirin or subcutaneous low-molecular weight heparin as appropriate. All drains were removed between twenty-four and forty-eight hours and patients were mobilised within one day of operation as pain allowed.

Patient demographics and operative details were gathered both from the patients' notes and from the ORSOS computerised theatre system.

Radiographic evaluation involved the Barrack[9] cementation grading system, Dorr's criteria[10,11] including varus/valgus alignment of the prosthesis and leg length measurement.. Measurements of length and varus/valgus were performed using the PACS (GE Medical Systems 2005) digital imaging system by two orthopaedic registrars independent of one another.

Finally all fifty patients were sent an Oxford Hip Score[12] at between two and four months postoperatively. Three patients died before the questionnaires were sent and of the remaining forty seven, there was a 98% response rate with 44 questionnaires completed solely by the patient and a further two completed with the aid of a carer.

RESULTS

1. Patient Demographics and operative details

Of the fifty patients in the study, thirty six were female and fourteen male. The mean age was 78 (range 38 to 99). Forty four ETS hemiarthroplasties were performed due to patient fitness and activity levels (Type 1 patients) with six undertaken in frail patients due to fracture extension into the calcar (Type 2). All type 1 patients were ASA grade 1 or 2 with all type 2 patients ASA grade 2-4. All type 1 patients had a mini-mental test score of 10/10 with type 2 patients ranging from 0-7.

The mean delay to surgery was 26 hours (9-58). Eight procedures were performed by consultants, thirty eight by registrars (training years three to six) and four by the trauma fellow under supervision by a senior. The mean operative time was sixty four minutes and the mean haemoglobin drop was 2.6 g/dl[3]. Seven patients required post operative transfusion of either two or three units of packed cells.

Thirty four of the patients mobilised unaided pre-injury with eight using one stick, four using two sticks and four using a frame. Using the four categories above, the average drop in mobility from injury to discharge was 1.6 levels.

The average hospital stay was 8.6 days (range 5-69) with thirty five patients discharged to their own house, four to their own residential home and eleven to a rehabilitation ward.

2. Radiographic Evaluation

The cement mantle was firstly evaluated using Barrack's grading:-

grade A: medullary canal completely filled w/ cement (white out).
grade B: a slight radiolucency exists at the bone cement interface.
grade C: a radiolucency of more than 50% at the bone cement interface.
grade D: radiolucency involving more than 100% of the interface between bone and cement in any projection, including absence of cement distal to the stem tip

Post-operative radiographic evaluation according to this system showed that 54% of cement mantles were Barrack grade B (27 cases) with the majority of the remainder grade C (12 cases) and grade A (eight cases). Two were graded as D.

Dorr's criteria were employed firstly to assess whether there was an adequate cement thickness of 3mm in Gruen zones 3 and 7 and of one centimetre distal to the tip of the prosthesis. Thirty-four prosthesis scored 3/3, nine scored two, four scored one and two scored none.

Dorr's criteria also assess position of the prosthesis using the AP radiograph. Ten prostheses were placed in a neutral position related to the femoral shaft. Seven were placed in 1-2 degrees of varus, twenty-seven were placed in 1-2 degrees of valgus and five were placed in 3-6 degrees of valgus.

There were equal leg length measurements in nineteen patients post-operatively with two patients left 5-10mm short on the operated side. Twenty-eight patients were left long with a mean lengthening of 12mm (5-30) and of these five were left between 20 and 30mm long one of which was irreducible and needed to be revised on the table.

3. Post-operative Scoring

The Oxford Hip Score contains 6 questions relating to pain and six relating to function and mobility which are scored 1 point for the best outcome and five for the poorest (Score 12-60). The average pain score was 12.0 and the average functional score was 15.2 giving an overall score of 27.2. The type 1 patients fared better with an average score of 25.3, the average score for type 2 patients was 44.3

4. Complications

The one immediate complication was the need for an on-table revision due to an irreducible prosthesis.

There was one superficial wound infection requiring antibiotic therapy and one early deep infection requiring open washout in theatre which resolved the infection in combination with antibiotic therapy.

There were three deaths (one CVA, one MI and one from pneumonia) all of which occurred between 30-90 days from the operative procedure.

DISCUSSION

The cohort of patients included in this study was similar to other studies with regards to male:female ratio, age and cognitive function[4,5]. The patients also experienced a delay to surgery and length of operation similar to previous studies[4,7]. The length of inpatient stay, however, was markedly better at 8.6 days compared to approximately fourteen to twenty-one days cited in the literature[13,14].

The length of operation, post-operative mobility and transfusion requirements were also similar to studies evaluating hemiarthroplasty outcomes[4,5].

Post-operative radiographic evaluation showed greater than 50% of cement mantles were Barrack grade B with the majority of the remainder grade C (24%) and A (16%). There was no statistical difference between our findings and those of an 8-12 year study of the Exeter stem in total hip replacement[15]. The two Barrack D grade cement mantles were in patients who became unwell intra-operatively and the decision was taken not to pressurise during cementation.

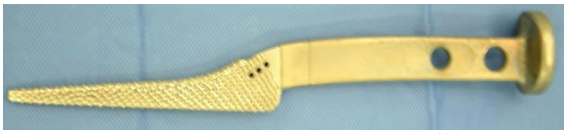

Figure 3: Original ETS broach with squared off handle, not allowing intra-operative trialling

The major difficulty evident from this study is the correct positioning of the ETS prosthesis with regards to restoration of accurate leg length which the authors believe was due to two reasons. Firstly, the original set for the Exeter Trauma Stem comes with one femoral broach (Fig 3) which does not allow trial reduction. Therefore positioning of the prosthesis required intra-operative estimation of the correct leg length which can be difficult with hip fractures as the leg length is abnormal at the commencement of surgery. Therefore the centre of rotation of the femoral head on the injured side was approximated by comparison with the contralateral side on the pelvic AP radiograph and referenced against the level of the greater trochanter during the procedure.

Secondly, because the large monoblock head of the ETS is matched to the patient's own femoral head anatomy, the

diameter of the ETS head is generally around 15-30mm wider than the 28mm heads commonly used with the Exeter stem in elective hip arthroplasty. Therefore care must be taken to sink the stem by a corresponding amount if a similar neck cut is used or the femoral neck osteotomy should be made at a more distal level. This often involves positioning the shoulder of the ETS stem below the level of the greater trochanter. This can mislead surgeons who are familiar with the Exeter stem as placing the ETS stem in a similar position to that employed with smaller head elective arthroplasty results in limb lengthening. Figure 4 shows a leg length discrepancy of 15mm despite a low neck cut as the stem has not been sunk sufficiently. This led to 56% of patients being left with true lengthening of the operated limb and one prosthesis irreducible. It is difficult to assess whether this is a common problem in the literature with other hemiarthroplasties used for femoral neck fractures as none of the comparable studies comment on clinical or radiographic assessment of leg length.

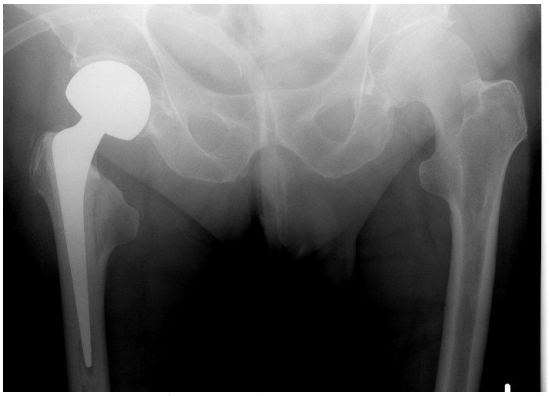

Figure 4: X-ray of ETS with limb lengthening. Although the neck cut has been made relatively low in relation to the lesser trochanter, the shoulder of the prosthesis slopes marginally above the greater trochanter, inadvertently lengthening the operated limb.

One major advantage to the tapered Exeter stem is the ease with which conversion to a total hip replacement can be performed using an in-cement technique[16]. Many of the patients included in this study were below the age of 70 and a proportion could be expected to outlive the prosthesis especially with regards to acetabular erosion[4]. Whilst none of this cohort has required revision for loosening, the irreducible Exeter implant was revised on-table using this technique without further complication.

Post operative Oxford Hip Scores were encouraging with no difference between our mean score of 27.2 and other studies evaluating both cemented hemiarthroplasty and total hip replacement following femoral neck fracture[12,17,18].

The mortality rate was 6% six to twelve months post surgery with all three deaths more than one month post surgery and apparently unrelated to the surgery itself. Overall mortality rates following neck of femur fracture are approximately thirty percent at one year however studies specifically looking at outcomes following cemented hemiarthroplasty in the fit and active patient have found mortality rates similar to this study[5,19].

Costing around £240, the ETS is a relatively cheap prosthesis in comparison to cemented bipolar prosthesis depite the additional expense of a cement restrictor, bone cement, cement gun and cement pressurisers.

In conclusion, the Exeter Trauma Stem (ETS) is an effective method of treating displaced intracapsular neck of femur fractures with encouraging post-operative functional, pain and radiographic scoring outcomes. The message highlighted by this study is that additional care is needed with regards to the correct positioning of the prosthesis to ensure the restoration of limb length. Subsequent to discussion with the Stryker representative regarding the results of this study, a second generation trialling system has been added to the set with a modular broach. The authors suggest that not only should these modular broaches be used, but also accurate pre-operative planning is needed to ensure equal leg lengths post-operatively.

Competing Interests
Author would like to state that none of the authors involved with this paper have any financial or personal relationship with Stryker or any other companies that could inappropriately influence this study.

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Research Article

BJMP 2010;3(1):306

Education in the Foundation Programme: what doctors are doing and why

MJ Keogh , JM Findlay , S Sithamparanathan and D Matheson

Abstract

The Foundation Programme details the first two years of training for UK doctors in the UK. Thereafter, trainees are expected to apply for highly competitive specialist training posts. Our study aimed to clarify and quantify the educational activities currently used by Foundation doctors during this two year period, and to assess their motivational and deterring factors towards such educational activities.

Method: A fourteen point questionnaire was posted at random to 100 Foundation Year 1 and 2 (50 FY1 and 50 FY2) doctors across five Trent Deanery hospitals. The questionnaire assessed involvement in the following voluntary educational activities: courses, conferences, higher qualifications, e-learning packages and personal reading. It also sought their underlying attitudes.

Results: Response rate was 49.0% (49/100), comprising 34 (68%) FY1 and 15 (30%) FY2. Overall 89.8% of respondents engaged in voluntary educational activities. The most common (89.8%) was the e-learning package (FY1 85.3%, FY2 100%) followed by society membership (73.5% (FY1 64.7%, FY2 93.3%), courses (69.4%) (FY1 55.9%, FY2 100%), sitting higher qualifications (36.7%) (FY1 14.7%, FY2 86.7%) and attending conferences (14.3%) (FY1 14.7%, FY2 13.3%). The mean total cost incurred by doctors for these activities was £581 in FY1 and £1842 in FY2.

The most common deterrents to pursuing voluntary education were a lack of study leave (42.9%) (FY1 38.2%, FY2 53.3%), lack of annual leave (22.4%) (FY1 23.5% FY2 20.0%) and expense (20.4%) (FY1 17.6%, FY2 26.7%).

The most common motivating factor was the belief they would help candidates achieve a specialist training post (67.3%) (FY1 58.8%, FY2 86.7%). Only 8.2% (FY1 11.8%, FY2 0.0%) engaged primarily to improve their medical competence.

Discussion: Our study is the first to quantify the voluntary educational activities of Foundation doctors. Most popular are e-learning packages — outstripping courses, higher qualification revision and conferences — highlighting their increasing popularity as a viable and accessible educational tool. The primary deterrent to pursuing voluntary educational activities is lack of study leave, of concern as entitlements to this continue to decrease. Interestingly, Foundation doctors are not motivated primarily by the educational benefits of these activities, but rather by their perceived ability to help attain a specialist training post. This highlights the concerning potential for voluntary educational activities to become a badge of attendance, undermining their intrinsic educational value and outcome.

The implementation of Modernising Medical Careers (MMC) significantly altered the structure of postgraduate medical education in the UK. MMC oversees the training of all UK doctors from the outset of their career, the first two years of which comprise the Foundation Programme. Successful completion of the Foundation Programme is based upon doctors' Foundation Portfolios in which they must demonstrate achievement of essential competences and work-based assessments. Doctors are also encouraged to attain additional competencies and to develop their portfolio further. Voluntary educational activities undertaken outside the workplace form the basis of this.

Application into Specialist Training following the Foundation Programme is highly competitive, with an average of three applicants for each post in 2008[1]. Points-based shortlisting criteria are used to select candidates, and are based upon the contents of the Foundation Portfolio and application form. This means that points can be scored for activities not required for completion of the Foundation Programme, such as Royal College membership examinations and course attendance. Foundation Programme doctors undertake voluntary activities to improve their portfolios however no quantifiable evidence currently exists as to what doctors undertake in this respect.

We aimed, therefore, to determine firstly what voluntary educational activities Foundation doctors are undertaking. We also aimed to establish their underlying motivating and deterring factors, financial costs incurred, and use of annual and study leave and 'specialty taster days', to assess the overall extent and impact of portfolio activities. The authors hope the results are useful in informing medical students and Foundation trainees of the scope of activities of their peers, and in advising supervisors of the activities of their trainees.

Methods

A two page anonymous questionnaire was posted at random to 100 Foundation doctors across five hospitals in East Midlands Deanery (50 Foundation Year 1, 50 Foundation Year 2). See Appendix 1

Demographics

The first section of the questionnaire asked for the sex and grade of respondents (Foundation Year 1 (FY1), or Foundation Year 2 (FY2))

Activities

Respondents were directly asked whether they were attending courses or conferences, using on-line e-learning packages,

joining professional bodies/societies or sitting higher professional examinations such as royal college membership examinations/higher degrees.

Cost

Doctors were asked how much money (excluding that of teaching allowances) and days of annual leave they used on the above activities. They were also asked how many of their allowed 'specialty taster days' they had taken during each year.

Motivating and deterring factors

Doctors were asked to rank from a list the motivating and deterring factors determining what activities they were undertaking.

Professional development

Doctors were finally asked to rank which educational activities they thought would make them a better overall Foundation doctor.

Results

Response rate was 49% with 49 doctors returning the questionnaire. Of these 69.4% (n=34) were Foundation Year 1 (FY1) and 30.6% (n=15) were Foundation Year 2 (FY2), with 53.1% female and 46.9% male.

Activities

Overall 89.8% (n=44) of respondents were engaged in voluntary educational activity (FY1 85.3%, FY2 100%). The most common mode (89.8%, n=44) was e-learning packages (FY1 85.3% (n=29), FY2 100% (n=15)) followed by joining/ becoming a member of professional bodies or societies ie BMA etc (73.5%, n=36) (FY1 64.7% (n=22), FY2 93.3% (n=14)), followed by courses (69.4%, n=34) (FY1 55.9% (n=19), FY2 100% (n=15)), undertaking higher qualifications (36.7%) (FY1 14.7% (n=5), FY2 86.7% (n=13)) and attending conferences (14.3%) (FY1 14.7% (n=5), FY2 13.3% (n=2))– See figure 1.

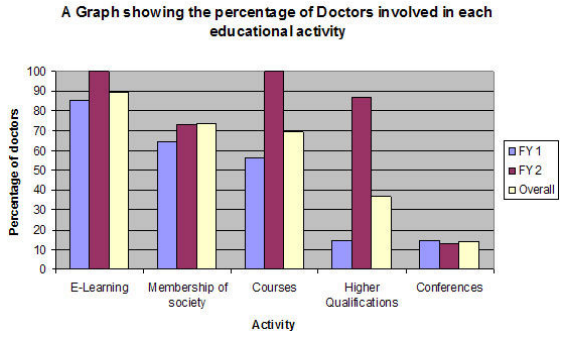

Fig 1 – A graph to show the percentage of Foundation year 1 and 2 doctors involved in each mode of voluntary educational activity.

Of the courses attended, 25.5% pertained to teaching, 25.5% to advanced life support and 18.0% to surgical skills. The remaining 31% of courses related to a variety of other interests such as anaesthetic skill days, expedition medicine courses, and sub speciality specific courses such as movement disorder workshops and laparoscopic surgery.

Cost

The mean amount spent by Foundation Year 1 Doctors on these activities was £581 (range £0 - £3100) Foundation Year 2 Doctors spent significantly more at £1842 (range £0 - £3500). The mean cost per activity is shown in figure 2.

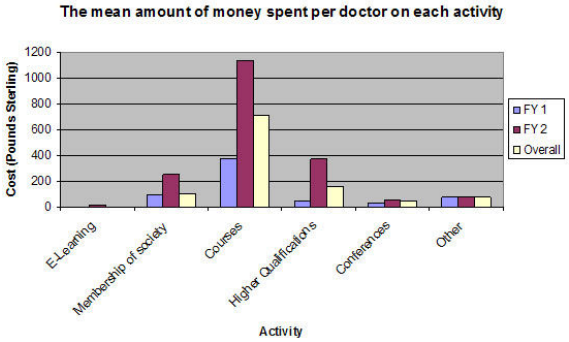

Fig 2 – A graph to show the mean amount of money spent by foundation year 1 and 2 doctors on each mode of educational activity.

The mean number of days of annual leave used by doctors for these activities was 2.8 in FY1 and 5.3 in FY2, therefore combining to average 8.1 days in total that would be used over the whole foundation programme. Of their five allowed 'taster – days' the mean number attended was 1.3 and 2.9 by FY1 and FY2 doctors respectively. Only 20.4% of doctors took their full entitled allowance.

Motivating and deterring factors

The most common factor motivating Foundation doctors to undertake portfolio educational activities was the belief they would help candidates achieve a specialist training post (67.3%). Only 12.2% engaged primarily out of personal interest with 8.2% to improve their medical competence (See Table 1).

The most common deterrents were a lack of study leave (42.9%), lack of annual leave (22.4%) and expense (20.4%) (See Table 2).

Professional development

The final section of the questionnaire asked respondents which educational activity they felt was most influential in making them a better Foundation doctor. Interestingly 83.7% (n=41)(FY1 88.2% (n=30), FY2 73.3%(n=11)) felt on-call experience was most influential, with only 6.1% (FY1 2.9%

(n=1), FY2 13.3% (n=2)) citing courses, 6.1 % (FY1 2.9% (n=1), FY2 13.3% (n=2)) e-learning packages and 4.1% (FY1 2.9% (n=1), FY2 6.7% (n=1)) qualifications (Fig 3).

Primary Motivating Factor	FY1		FY2		Overall	
	(%)	n	(%)	n	(%)	n
Improve chance of specialist training post	58.8	20	86.7	13	67.3	33
Personal interest	14.7	5	6.7	1	12.2	6
To improve medical competencies	11.8	4	0	0	8.2	4
On advice of seniors	11.8	4	6.7	1	10.2	5
Other	2.9	1	0	0	2	1
TOTAL	100	34	100	15	100	49

Table 1 – A table to show the primary motivating factors of foundation doctors to undertake voluntary portfolio educational activities.

Primary Deterring Factor	FY1 Doctors		FY2 Doctors		Overall	
	(%)	n	(%)	n	(%)	n
Lack of study leave	38.2	13	53.3	8	42.9	21
Lack of annual leave	23.5	8	20	3	22.4	11
Financial expense	17.6	6	26.7	4	20.4	10
Lack of career choice	11.8	4	0	0	8.2	4
Not relevant to Foundation doctors	8.8	3	0	0	6.1	3
Other	0	0	0	0	0	0
TOTAL	100	34	100	15	100	49

Table 2 – A table to show the primary deterring factors listed by foundation doctors that deter them from undertaking voluntary educational portfolio activities.

Professional development

The final section of the questionnaire asked respondents which educational activity they felt was most influential in making them a better Foundation doctor. Interestingly 83.7% (n=41)(FY1 88.2% (n=30), FY2 73.3%(n=11)) felt on-call experience was most influential, with only 6.1% (FY1 2.9% (n=1), FY2 13.3% (n=2)) citing courses, 6.1 % (FY1 2.9% (n=1), FY2 13.3% (n=2)) e-learning packages and 4.1% (FY1 2.9% (n=1), FY2 6.7% (n=1)) qualifications (Fig 3).

The academic conference was ranked least influential by 89.8% (n=44) (FY1 85.3% (n=29), FY2 100% (n=15)) of respondents, followed by 6.1% (n=3) (FY1 8.8% (n=3), FY2 0.0% (n=0)) citing courses, and 4.8% (FY1 5.8% (n=2), FY2 0.0% (n=0)) e-learning packages (Fig 3).

Discussion

This survey suggests that Foundation doctors undertake numerous activities at significant personal expense to expand their portfolios, and are primarily motivated by a belief that this will increase their chance of obtaining higher specialist training posts.

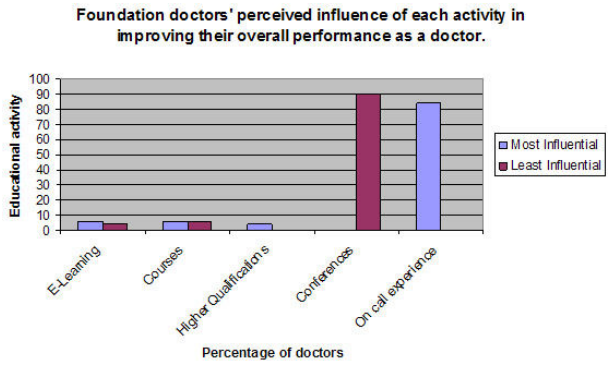

Fig 3 – The above graph was the response of Foundation doctors when asked which activities they thought were most and least influential in making them a better foundation doctor.

Educational activities and opportunities

The advent of the *European Working Time Directive* and *New Deal* document[2] have resulted in junior doctors working considerably fewer hours than in previous years. This has led some authors to conclude that the quality of learning opportunities in the working environment has reduced [3] .With 89.8% of Foundation doctors in this survey actively undertaking some form of educational activity outside of work, this suggests that Foundation doctors may be going some way to re-dressing this balance. It may also come as a surprising yet reassuring figure to Foundation Programme educational supervisors who may be unaware of the education of their trainees outside of work.

We found the most popular mode of educational activity to be the e-learning package. E-learning is an effective and extensively employed method for both distance learning[4], and as an adjunct to "traditional" lecture-based techniques across several disciplines. It has also been shown to be a well received and practical method of supplementary education for doctors[5] and our study suggests this is particularly true for the Foundation years. The reasons why e-learning is popular in this group was not explored, but its low cost, easily accessible and modular nature may have some part to play. As medical schools continue to utilise this modality to a greater extent, its follow-through into the Foundation years and postgraduate medical education in general is inevitable. With such high uptake, e-learning packages are a promising format for delivering education to this group.

Popular courses undertaken by Foundation doctors related to obtaining teaching skills, or advanced life support. This suggests that Foundation doctors place a high emphasis on teaching and training, and on recognising and managing acutely ill patients. These are two core objectives of the Foundation Programme. However, one could also argue that doctors undertaking courses outside work to achieve essential competencies casts doubt on the ability of the Foundation Programme to deliver them. We

submit that educational supervisors are in a prime position to appraise this issue.

The least popular mode of activity in our survey was the attendance of a medical conference. It was also regarded as least influential by 89.7% of respondents. There is a global shortage of medical academics[6], and as conferences serve to introduce junior doctors to academic medicine and research, perhaps academic doctors should take a more prominent role in promoting conferences as an educational activity.

Time and money

Doctors incur the majority of their costs attending courses with Foundation Year 1 and 2 doctors spending £365 and £1120 respectively on this area (fig 2). This highlights the possibility that Foundation doctors may be prone to financial exploitation by a growing number of courses which are often unvalidated. As senior advice was the primary motivating factor for only 10.2% of activities, this suggests that educational supervisors could play a greater role in assessing, appraising and advising their trainees on the courses best suited for them and their professional development.

The overall financial cost incurred for all portfolio educational activities was £581 for FY1 and £1842 for FY2. Whilst previous estimates have been made in this area, this is the first specific to the Foundation Programme and to include non-mandatory outlay, and represents 3 % and 7% of the basic salary for FY1 and FY2 doctors before tax. As our survey found financial expense to be a significant deterrent to portfolio activity (20.4% of respondents), a potentially serious implication is that expense will limit the uptake of postgraduate education in the future. From the authors' own experience such professional costs are not explained to medical students and that this issue merits more attention in undergraduate education.

A lack of study leave was highlighted as the main deterring factors to educational portfolio activities (42.9%). This is of particular interest as only 20.4% of Foundation doctors use their full 'taster-day' entitlement. These 'taster days' are a fundamental aspect of the Foundation Programme, offering doctors the opportunity to explore a specialty for up to five days per year. However, whilst doctors fail to utilise them, they take an average of 8.1 days' annual leave over the two year programme for educational purposes.

The reasons behind this are unclear, but may be due to a lack of awareness of these 'taster days'. With a lack of study leave hindering educational activities, a potential solution might be for doctors to have the option to utilise 'taster days' as a form of study leave.

Professional education and motivation

Between 1998 and 2005, the number of medical students in the UK has risen by 57%[7]. Increasing numbers of doctors and decreasing working hours may reduce the amount of on-call experience for those in the Foundation Programme. However, it is this on-call experience that is regarded by the vast majority (83.7% in this study) as the most important educational modality in making them a better foundation doctor. Although time and money are perceived as barriers to portfolio educational activities it appears that doctors value this on-call experience above all. With key aims of the Foundation Programme being training and emergency competence, efforts must be made to preserve this experience.

Whilst Foundation doctors are engaging in numerous portfolio activities, their underlying motivations are interesting. It appears this group are primarily motivated not by the educational benefits of these activities, but rather by their perceived ability to help attain a specialist training post. This could suggest that the educational portfolio is at risk of becoming a 'tick-box' means for career progression, rather than addressing limitations, exploring interests and aspiring to clinical excellence. This contrasts with the conclusions of the most recent assessment of postgraduate medical education in the UK[8].

As competition for jobs appears to be driving Foundation doctors to undertake educational activities it remains unclear whether engaging in these activities to obtain jobs, rather than competencies, reduces their validity and educational outcomes. Furthermore it is unclear whether trainees will be more likely to achieve their overriding aim of obtaining a specialist training post through these activities. Determining the career outcomes of doctors undertaking these activities will provide an evidence base, allowing educational supervisors to optimally advise their trainee in portfolio educational activities.

Conclusions

This is a baseline survey quantifying portfolio educational activities in the Foundation Programme, applicable to trainees and supervisors alike. Whilst the latter are well aware of assessments such as DOPS (Direct Observation of Procedural Skills) and CbD's (Case-based Discussions), they are often less aware of the voluntary educational activities of their trainees.

Our study would suggest that Foundation Programme doctors are a cohort driven to undertake numerous voluntary educational activities, albeit largely to achieve career progression rather than accrue educational benefit. To this end they undertake activities such as e-learning, courses and higher qualifications at the expense of conferences. For this they spend significant amounts of money and leave, yet continue to site a lack of traditional study leave as a barrier to further educational development. The authors would suggest that further work is needed to develop the role of educational supervisors in the Foundation Programme in harnessing the motivation of their trainees, and guiding them appropriately.

Key Points

- Foundation Doctors spend significant amounts of time and money on voluntary educational activities.
- Foundation Doctors are primarily driven to undertake these activities due to the belief that it will help them obtain specialist training posts.
- A lack of study leave is the primary barrier to voluntary education.
- The academic medical conference is viewed as the activity least likely to improve medical competence, whereas on-call experience is regarded as the most likely.
- Foundation Programme educational supervisors are best placed to guide their trainees towards the most appropriate educational modalities

Competing Interests
None Declared

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Appendix 1
Educational Activities in the Foundation Programme – Questionnaire

What is your current grade (F1 or F2)? F1 ☐ F2 ☐
What sex are you ? Male ☐ Female ☐

1) Which of the following educational activities have you undertaken as an F1/F2 Doctor outside of that deemed mandatory by your employing deanery or hospital?
Completed Online/e-learning packages ☐
Which? _____
What was the personal financial cost to you? _____
Attended courses (eg ATLS, ALS etc) ☐
Which?_____
What was the personal financial cost to you? _____
Attended local, regional or national conferences ☐
Which? _____
What was the personal financial cost to you?_____
Attempted higher academic qualifications eg MRCP, MRCS exams ☐
Which? _____
What was the personal financial cost to you? _____
Joined any professional bodies or societies ☐
Which? _____
What was the personal financial cost to you? _____

2) **From the list below, please choose the option that has most strongly motivated you to undertake the activities you have outlined in question 1**
To further my personal knowledge/interest in an area☐
To improve my overall ability/achieve my competencies as Foundation Doctor ☐
To increase my chance of obtaining a specialist training (ST1) post in my chosen area☐
I have been advised to undertake certain activities by seniors ☐
Free text/other _____

3) From the list below, please choose the main reason why you have not engaged in further educational activities to those you listed in question 1
Due to financial expense ☐
There is a lack of study leave ☐
There is a lack of annual leave ☐
I am still not decided on a firm career choice ☐
I don't think these activities are needed by Foundation doctors. ☐
Other _____

4) From the list of choices below, please mark which activity you feel will most improve your overall ability as a foundation doctor, and which you feel will have the least effect? (Please respond with 'M' for most and 'L' for least)
Online/e-learning packages ☐
Attending courses (eg ATLS, ALS etc) ☐
Attending local, regional or national conferences ☐
Sitting higher academic qualifications eg MRCP, MRCS exams ☐
On call in hospital experience ☐

5) How many of your allowed specialty taster days have you used this year?
_____

6) How many days of annual leave/ holiday have you used this year to undertake voluntary educational activities?
_____

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Research Article

Predictors of Difficult Intubation: Study In Kashmiri Population

Arun Kr. Gupta , Mohamad Ommid , Showkat Nengroo , Imtiyaz Naqash and Anjali Mehta

Abstract

Airway assessment is the most important aspect of anaesthetic practice as a difficult intubation may be unanticipated. A prospective study was done to compare the efficacy of airway parameters to predict difficult intubation. Parameters studied were degree of head extension, thyromental distance, inter incisor gap, grading of prognathism, obesity and modified mallampati classification. 600 Patients with ASA I& ASA II grade were enrolled in the study. All patients were preoperatively assessed for airway parameters. Intra-operatively all patients were classified according to Cormack and Lehane laryngoscopic view. Clinical data of each test was collected, tabulated and analyzed to obtain the sensitivity, specificity, positive predictive value & negative predictive value. Results obtained showed an incidence of difficult intubation of 3.3 % of patients. Head and neck movements had the highest sensitivity (86.36%); high arched palate had the highest specificity (99.38%). Head and neck movements strongly correlated for patients with difficult intubation.

KEYWORDS

Intubation, Anaesthesia, Laryngoscopy

Introduction

The fundamental responsibility of an anesthesiologist is to maintain adequate gas exchange through a patent airway. Failure to maintain a patent airway for more than a few minutes results in brain damage or death[1]. Anaesthesia in a patient with a difficult airway can lead to both direct airway trauma and morbidity from hypoxia and hypercarbia. Direct airway trauma occurs because the management of the difficult airway often involves the application of more physical force to the patient's airway than is normally used. Much of the morbidity specifically attributable to managing a difficult airway comes from an interruption of gas exchange (hypoxia and hypercapnia), which may then cause brain damage and cardiovascular activation or depression[2].

Though endotracheal intubation is a routine procedure for all anesthesiologists, occasions may arise when even an experienced anesthesiologist might have great difficulty in the technique of intubation for successful control of the airway. As difficult intubation occurs infrequently and is not easy to define, research has been directed at predicting difficult laryngoscopy, i.e. when is not possible to visualize any portion of the vocal cords after multiple attempts at conventional laryngoscopy. It is argued that if difficult laryngoscopy has been predicted and intubation is essential, skilled assistance and specialist equipment should be provided. Although the incidence of difficult or failed tracheal intubation is comparatively low, unexpected difficulties and poorly managed situations may result in a life threatening condition or even death[3].

Difficulty in intubation is usually associated with difficulty in exposing the glottis by direct laryngoscopy. This involves a series of manoeuvres, including extending the head, opening the mouth, displacing and compressing the tongue into the submandibular space and lifting the mandible forward. The ease or difficulty in performing each of these manoeuvres can be assessed by one or more parameters[4].

Extension of the head at the atlanto-occipital joint can be assessed by simply looking at the movements of the head, measuring the sternomental distance, or by using devices to measure the angle[5]. Mouth opening can be assessed by measuring the distance between upper and lower incisors with the mouth fully open. The ease of lifting the mandible can be assessed by comparing the relative position of the lower incisors in comparison with the upper incisors after forward protrusion of the mandible[6]. The measurement of the mento-hyoid distance and thyromental distance provide a rough estimate of the submandibular space[7]. The ability of the patient to move the lower incisor in front of the upper incisor tells us about jaw movement. The classification provided by Mallampati et al[8] and later modified by Samsoon and Young[9] helps to assess the size of tongue relative to the oropharynx. Abnormalities in one or more of these parameters may help predict difficulty in direct laryngoscopy[1].

Initial studies attempted to compare individual parameters to predict difficult intubation with mixed results[8,9]. Later studies have attempted to create a scoring system[3,10] or a complex mathematical model[11,12]. This study is an attempt to verify which of these factors are significantly associated with difficult exposure of glottis and to rank them according to the strength of association.

Materials & methods

The study was conducted after obtaining institutional review board approval. Six hundred ASA I & II adult patients, scheduled for various elective procedures under general anesthesia, were included in the study after obtaining informed consent. Patients with gross abnormalities of the airway were excluded from the study. All patients were assessed the evening before surgery by a single observer. The details of airway assessment are given in Table I.

Table I: Method of assessment of various airway parameters (predictors)

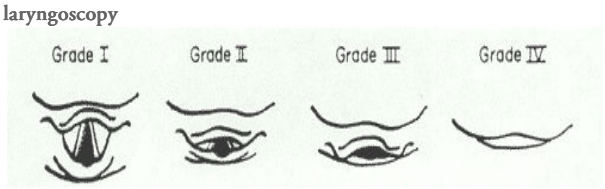
Airway Parameter	Method of assessment
Modified Mallampati Scoring	Class I: Faucial pillars, soft palate and uvula visible. Class II: Soft palate and base of uvula seen Class III: Only soft palate visible. Class IV: Soft palate not seen Class I & II : Easy Intubation Class III & IV: Difficult Intubation
Obesity	Obese BMI (≥ 25) Non Obese BMI (< 25)
Inter Incisor Gap	Distance between the incisors with mouth fully open(cms)
Thyromental distance	Distance between the tip of thyroid cartilage and tip of chin, with fully extended(cms)
Degree of Head Extension	Grade I ≥ 90° Grade II = 80°-90° Grade III < 80°
Grading of Prognathism	Class A: - Lower incisor protruded anterior to the upper incisor. Class B: - Lower incisor brought edge to edge with upper incisor but not anterior to them. Class C: - Lower incisors could be brought edge to edge.

In addition the patients were examined for the following.

- High arched palate.
- Protruding maximally incisor (Buck teeth)
- Wide & short Neck

Direct laryngoscopy with Macintosh blade was performed by an anaesthetist who was blinded to preoperative assessment. Glottic exposure was graded as per Cormack-Lehane classification[13] (Fig 1).

Figure 1: Cormack-Lehane grading of glottic exposure on direct laryngoscopy



Grade 1: most of the glottis visible; Grade 2: only the posterior extremity of the glottis and the epiglottis visible; Grade 3: no part of the glottis visible, only the epiglottis seen; Grade 4: not even the epiglottis seen. Grades 1 and 2 were considered as 'easy' and grades 3 and 4 as 'difficult'.

Results

Glottic exposure on direct laryngoscopy was difficult in 20 (3.3%) patients. The frequency of patients in various categories of 'predictor' variables is given in Table-II.

The association between different variables and difficulty in intubation was evaluated using the chi-square test for qualitative data and the student's test for quantitative data and $p<0.05$ was regarded as significant. The clinical data of each test was used to obtain the sensitivity, specificity and positive and negative predictive values. Results are shown in Table III.

Table II: The frequency analysis of predictor parameters

Airway Parameter	Group	Frequency(%)
Modified Mallampati Scoring	Class 1&2 Class 3&4	96% 4%
Obesity	Obese BMI (≥ 25) Non Obese BMI (< 25)	28.7% 71.3%
Inter Incisor Gap	Class I : >4cm Class II: <4cm	93.5% 6.5%
Thyromental distance	Class I: ≥ 6cm. Class II: ≤6cm.	94.6% 5.4%
Head & Neck Movements	Difficult {class II & III (90°)} Easy {class I(>90°)}	16% 84%
Grading of Prognathism	Difficult (class III) Easy (class I + II)	96.1% 3.9%
Wide and Short neck	Normal neck body ratio 1:13 Difficult (Ratio≥ 1:13)	86.9% 13.1%
High arched Palate	Yes No	1.9% 98.1%
Protruding Incisors	Yes No	4.2% 95.8%

Table III: Comparative analysis of various physical factors and scoring systems

Physical factors and various Scoring Systems	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Obesity	81.8	72.76	6.34	99.43
Inter incisor gap	18.8	94.14	6.6	98.1
Thyromental distance	72.7	96.5	32.0	99.4
Head and Neck movement	86.36	86.0	34.6	99.7
Prognathism	4.5	96.3	2.7	97.9
Wide and Short neck	45.5	87.9	7.8	98.6
High arched palate	40.1	99.38	60.0	98.67
Protruding incisor	4.6	95.9	2.5	97.79
Mallampati scoring system	77.3	98.2	48.57	99.5
Cormack and Lehane's scoring system	100	99.7	88	100

Discussion

Difficulty in endotracheal intubation constitutes an important cause of morbidity and mortality, especially when it is not anticipated preoperatively. This unexpected difficulty in intubation is the result of a lack of accurate predictive tests and inadequate preoperative assessment of the airway. Risk factors if identified at the preoperative visit help to alert the anaesthetist so that alternative methods of securing the airway can be used or additional expertise sought before hand.

Direct laryngoscopy is the gold standard for tracheal intubation. There is no single definition of difficult intubation but the ASA defines it as occurring when "tracheal intubation requires multiple attempts, in the presence or absence of tracheal pathology". Difficult glottic view on direct laryngoscopy is the most common cause of difficult intubation. The incidence of difficult intubation in this study is similar to that found in others.

As for as the predictors are concerned, different parameters for the prediction of difficult airways have been studied. Restriction of head and neck movement and decreased mandibular space have been identified as important predictors in other studies. Mallampati classification has been reported to be a good predictor by many but found to be of limited value by others[14]. Interincisor gap, forward movement of jaw and thyromental distance have produced variable results in predicting difficult airways in previous studies[7,15]. Even though thyromental distance is a measure of mandibular space, it is influenced by degree of head extension.

There have been attempts to create various scores in the past. Many of them could not be reproduced by others or were shown to be of limited practical value. Complicated mathematical models based on clinical and/or radiological parameters have been proposed in the past[16], but these are difficult to understand and follow in clinical settings. Many of these studies consider all the parameters to be of equal importance.

Instead of trying to find 'ideal' predictor(s), scores or models, we simply arranged them in an order based on the strength of association with difficult intubation. Restricted extension of head, decreased thyromental distance and poor Mallampati class are significantly associated with difficult intubation.

In other words patients with decreased head extension are at much higher risk of having a difficult intubation compared to those with abnormalities in other parameters. The type of equipment needed can be chosen according to the parameter which is abnormal. For example in a patient with decreased mandibular space, it may be prudent to choose devices which do not involve displacement of the tongue like the Bullard laryngoscope or Fiber-optic laryngoscope. Similarly in patients with decreased head extension devices like the McCoy Larngoscope are likely to be more successful.

Conclusion

This prospective study assessed the efficacy of various parameters of airway assessment as predictors of difficult intubation. We have find that head and neck movements, high arched palate, thyromental distance & Modified Malampatti classification are the best predictors of difficult intubation.

Competing Interests
None Declared
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Research Article

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A comparison of different methods of assessing cosmetic outcome following breast-conserving surgery and factors influencing cosmetic outcome

Charfare H, MacLatchie E, Cordier C, Bradley M, Eadie C, Byrtus A, Burnet K, Chapman D, Wishart GC, Purushotham AD

Abstract

Methods to assess cosmesis following breast-conserving surgery are varied and assumed to yield similar results. The aim of this study was to compare three different methods of cosmetic assessment following breast-conserving surgery and to assess the impact of certain factors on cosmetic outcome.

One hundred and fifteen patients undergoing breast-conserving surgery had 3 view digital photographs taken for assessment of cosmesis at one year post-surgery. Subjective cosmetic assessment was performed by a 5 member panel and objective assessment by Breast Retraction Assessment (BRA) and Nipple Deviation (ND). Factors including tumour size, percentage breast volume excised, location of tumour and number of breast operations performed was correlated with final cosmetic outcome.

The majority of patients undergoing breast-conserving surgery demonstrated satisfactory cosmetic results. Inter-observer variation assessed using a kappa statistic for panel assessment gave a value of 0.42 with a 95% confidence interval (CI) of 0.37 to 0.47, indicating moderate agreement between observers. The kappa statistic for agreement between the three methods used for assessing cosmesis was -0.23 with 95% CI of -0.35, -0.11 indicating poor concordance between the three methods used. These methods however, may be complementary to each other and therefore these observations merit further investigation. Tumour location, tumour size and the number of operations performed did not influence cosmetic outcome. However, cosmetic outcome was related to percentage breast volume excised.

Keywords: breast-conserving surgery, cosmetic assessment

Introduction:

Cosmetic outcome following breast-conserving surgery depends on various factors including location of the tumour, weight of the specimen excised, number of surgical procedures, volume of breast, length of scar and postoperative adjuvant treatment[1]. The best method of cosmetic assessment following breast-conserving surgery is still unclear. However various objective and subjective methods in combination are known to give a good assessment of cosmesis[2, 3, 4]. It has been shown that photographic assessment is as effective as live assessment in the post-surgical setting[5]. Methods to assess cosmesis following breast-conserving surgery are varied and more recently computer software are being used to assess cosmesis following breast-conserving surgery.

The aim of this study was to compare three different methods of cosmetic assessment following breast-conserving surgery and to assess the influence of various factors on final cosmetic outcome.

Methods:

One hundred and fifteen patients underwent breast-conserving surgery for carcinoma of breast by wide local excision and level 2 axillary clearance. Following wide local excision, cavity shavings were taken to ensure adequate local excision. Breast drainage was not used but suction drains were used routinely following axillary clearance. All patients received adjuvant breast radiotherapy (46 Gy, 23 fractions with a cavity boost of 12 Gy in 4 fractions) administered over a period of 6 weeks.

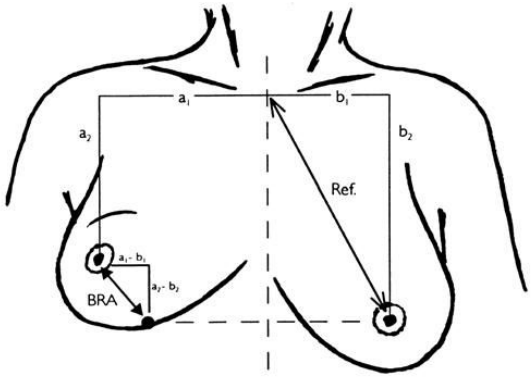

Fig. 1. Illustration of the BRA measurements.

$$BRA = \sqrt{(a_1 - b_1)^2 + (a_2 - b_2)^2};$$

Figure-1: Measurement of Breast Retraction Assessment[6] (reprinted with permission from Elsevier, ref 6 (page 670), copyright 1999)

Digital photographs were taken at one year in three views; frontal with arm by the side, frontal and oblique with arm abducted to 90 degrees. The photographs were used for subjective and objective assessment of cosmesis. The objective assessment of cosmesis was carried out using Breast Retraction

Assessment (BRA) and Nipple Deviation (ND). BRA was calculated as indicated in figure 1[6]. ND was calculated as a percentage difference from suprasternal notch to nipple on normal side compared with the operated side. BRA and ND were then categorised into three groups; BRA: (excellent to good <3.1 cm, fair 3.1-6.5, poor >6.5), ND: (difference of <5% - excellent to good, 5-10% fair and >10% poor). Subjective assessment was carried out using a panel consisting of a Consultant Breast Surgeon, Research Fellow, Secretary, Breast Care Nurse and Nurse Practitioner with each scoring independently. The method described by Harris et al[7] with a score of 9-10 for excellent (no visible difference between two breasts), good (slight difference; score 7-8), fair (obvious difference but no major distortion; score 4-6) and poor (major distortion; score <4) was used to categorise patients.

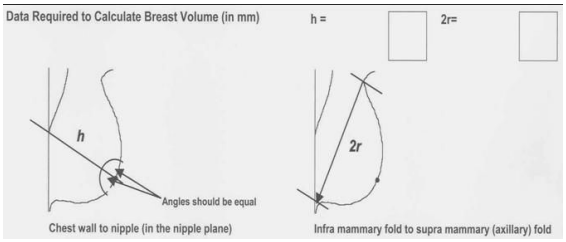

Figure- 2: Measurement of breast volume (Sloane method) Formula for calculation of breast volume: 1/3 π r^2h (reprinted with kind permission from Sloane project)

The volume of breast tissue excised was estimated with the length (L), width (W) and height (H) of the excised tissue specimen and the cavity shave measured by the pathologist and using the formulas for a prolate ellipse (V= 0.52* L* W* H); this was added on to the volume of cavity shave calculated using the formula 0.79* L* W* H. The total breast volume was estimated using the mammogram and applying the formula (1/3 πr^2h) as shown in figure-2. Based on these measurements the percentage breast volume excised was calculated and compared with cosmetic outcome.

Statistics:

Multirater kappa statistics[8] were used to assess inter-observer agreement between five different members of the panel and also to test agreement between the three different methods for assessing cosmesis. The average value given by the panel was used and categories good and excellent were combined in order to compare the three methods of cosmetic assessment. A kappa statistic of less than or equal to 0.20 was considered to demonstrate poor agreement, 0.21 to 0.40 fair agreement, 0.41 to 0.60 moderate agreement, 0.61 to 0.80 good agreement and 0.81-1.00 very good agreement[9].

The effect of the percentage volume of the breast tissue excised and the tumour size on the three methods of cosmetic assessment was examined using where appropriate a Jonckhneere-Terpstra test for trend, a Kruskal Wallis test or a Mann-Whitney U test. The effect of the number of breast operations performed and the location of the tumour were assessed using Chi-square test or Fisher's exact test when appropriate.

Results:

Of the 115 patients assessed using panel assessment 64 (56%) scored good to excellent, 39 (34%) scored fair and 12 (10%) scored poor. ND scored 50(43%) as good to excellent, 32 (28%) as fair and 33 (29%) as poor. Using BRA, the scores were 76 (66%), 38 (33%) and 1(1%) respectively. These results are shown graphically in figure-3.

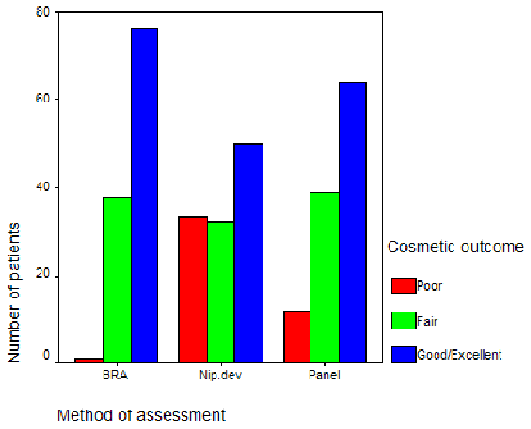

Figure- 3: Number of patients classified into each of the three categories poor, fair and good/excellent for the three methods bra, nipple deviation and panel assessment. BRA= breast retraction assessment; Panel= assessment by different panel members; ND= nipple deviation

Taking the mean scores for these three methods of assessment and dichotomising the results into two categories of good to excellent and poor to fair, 52% of patients in this study had good to excellent cosmetic result and 48% were categorised as fair to poor cosmetic result. The Kappa statistic was calculated on 115 patients for the three methods of assessment and it was found to have a value of –0.23 (95% CI (–0.35, – 0.11) which falls within the poor agreement category.

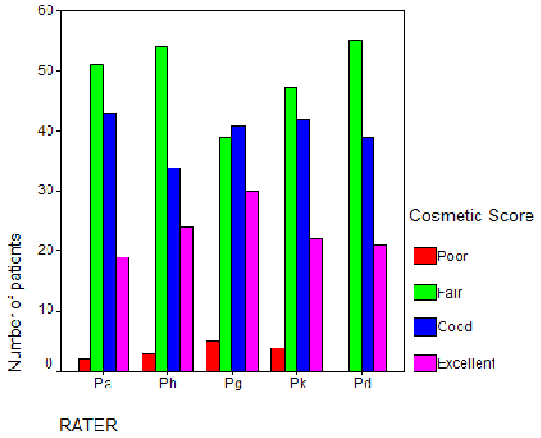

Figure- 4: Comparison of panel assessment by different panel members. Pa, Ph, Pg, Pk and Pd= Codes for the different panel members

Examining the panel assessment using the kappa statistics for the 115 patients assessed there was moderate agreement between the panel members (Kappa statistic of 0.42; 95% confidence interval of (0.37, 0.47). This suggests there is moderate chance that the panel members will categorise each patient the same way. If one plots the panel assessment graphically one can see that excellent is used least by all and fair most frequently (figure 4).

Factors affecting cosmesis:

1) Percentage breast volume excised

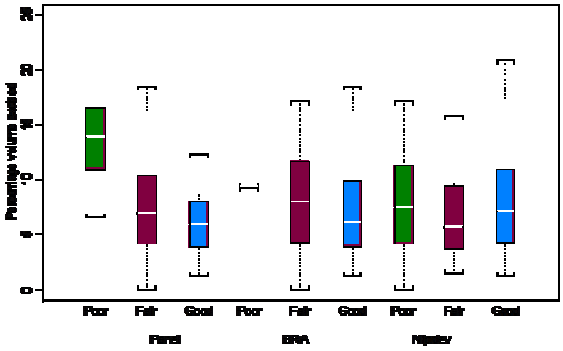

Figure -5: Effect of percentage breast volume excised on cosmetic outcome using Panel assessment, BRA and ND

For panel assessment it appears that removal of a larger percentage volume gives a poor cosmetic result and a smaller percentage volume an excellent/good result (figure 5) as would be expected clinically. This is supported by a Jonckhneere-Terpstra test for trend (=0.01). Using ND median percentage volumes across the groups did not appear to differ (χ^2=1.05 p=0.59, Kruskal Wallis test). However, for BRA, only one patient was classified as poor and no difference was seen between those with fair and good/excellent results (U=477, p=0.34). The median volume excised for different cosmetic outcome using the three methods is shown in table 1.

Table-1: Medians volumes for the three measurements.

	Panel assessment	BRA	Nipple deviation
Poor	157.56	(1 poor value)	100.61
Fair	88.58	93.11	55.96
Good/Excellent	68.33	76.55	81.33

BRA= breast retraction assessment

The percentage breast volume excised was then compared with cosmetic outcome using the three methods of assessment. As shown in table 2, 45-65% of patients with <10% estimated breast volume excised had good to excellent cosmetic result compared with 35-50% good to excellent result if >10% breast volume was excised.

2) Tumour location:

Tumour location was divided into inner or outer quadrants of the breast. The distribution of tumours in the breast and the cosmetic outcome with each of the three methods of assessment is shown in table 3. The location of tumour within the breast was not significantly associated with cosmetic outcome (χ^2 =1.86, p=0.39 for panel assessment), (p=0.23, Fisher's exact test for BRA) and (χ^2 =0.21, p=0.90 for ND).

Table-2: Estimated percentage breast volume excised and cosmetic outcome

	< 10% breast volume excised	> 10% breast volume excised
Panel Assessment		
Good to excellent (%)	32 (65)	7 (35)
Fair (%)	15 (31)	6 (30)
Poor (%)	2 (4)	7 (35)
Breast Retraction Assessment		
Good to excellent (%)	32 (65)	10 (50)
Fair (%)	16 (33)	10 (50)
Poor (%)	1 (2)	0
Nipple Deviation		
Good to excellent (%)	22 (45)	8 (40)
Fair (%)	15 (31)	4 (20)
Poor (%)	12 (24)	8 (40)

3) Number of breast operations:

The influence of number of operations (1 vs 2) was examined for each of the three methods of assessment. Using BRA and Panel assessment there was no significant difference in the cosmetic outcome for patients who underwent one or two operations (p=0.70 for panel assessment), (p=0.99, Fisher's exact test for BRA). For ND there does appear to be a larger proportion in the poor group for those with two operations (p =0.30 Fisher's exact test for ND). This is illustrated in Table 3.

Table-3: Factors affecting cosmesis

	Panel	BRA	ND
Percentage volume excised			
Poor (median (IQR))	13.8(11.0,16.5)	-	8.5 (5.1,11.4)
Fair (median (IQR))	8.4 (4.4,10.4)	8.0 (4.6,11.6)	5.8 (3.9,9.4)
Good/Excellent (median (IQR))	5.8 (3.9,8.0)	6.9 (4.3,10.1)	7.2 (4.4,11.0)
Location			
Poor (outer (n), inner (n))	8, 2	0,1	9,1
Fair (outer (n), inner (n))	22,8	26,5	23,6
Good/Excellent (outer (n), inner (n))	47,8	51,12	33,8
No. of Operations			
Poor (One (n), Two (n))	9,1	1,0	20,5
Fair (One (n), Two (n))	24,6	26,5	27,2
Good/Excellent (One (n), Two (n))	48,8	54,10	34,8
Tumour size (mm)			
Poor (median (IQR)	12 (9, 15)	-	12 (10, 15)
Fair (median (IQR)	11 (9, 19)	11 (8,15)	12 (8, 16)
Good/ Excellent (median (IQR)	12 (7, 15)	12 (7, 15)	9 (6,14)

Panel= panel assessment; BRA= breast retraction assessment; ND= nipple deviation; IQR= inter quartile range

4) Tumour size:

Table 3 shows the median tumour size and interquartile range for the three categories, good/ excellent, fair and poor and one

can see that there is no significant difference in tumour size for these categories using panel assessment (Jonckheere-Terpstra p=0.31) or BRA (U =873, p=0.55). However, using ND there was evidence to suggest that large tumour size resulted in poor outcome (Jonckheere-Terpstra, p=0.04).

Thus, tumour size had a significant influence on the cosmetic outcome when ND was used as the method of assessment.

Discussion:

Cosmetic outcome following breast-conserving surgery is assessed using a combination of subjective and objective methods. The subjective method uses a panel of members from different backgrounds to assess overall cosmesis. However, Pezner et al[10] showed relatively low level of agreement between observers when a four-point scale was used for assessment of overall cosmesis. The objective methods, which mainly compare the position of the nipple, are easy to reproduce but do not take into account skin changes and give poor assessment of cosmesis for lower quadrant tumours.

In this study the cosmetic outcome was assessed in 115 patients one year post-operatively. The mean cosmetic result using the three different methods of assessment was good to excellent in 55% of the patients, which compares favourably with other studies reported in the literature[2, 4]. Looking at inter-observer variation for the panel assessment, moderate agreement was found between different panel members. This compares favourably with an earlier study that looked at cosmetic outcome in the EORTC trial 22881/10882[6]. However, when the three methods of cosmetic assessment were compared with each using kappa statistic there was poor concordance. Although some agreement was noted, this was likely to be due to chance as the kappa statistic was low. It is difficult to explain this finding as other authors[1, 6] have reported moderate to good agreement between subjective and objective methods. One explanation for this lack of agreement is that each method assesses a different aspect of cosmesis.

The two objective methods of cosmetic assessment (BRA and ND) that are used to assess upward retraction of nipple have been found to be a very good determinant of cosmetic outcome and are easy to reproduce according to Fujishiro et al[11]. Furthermore, evaluation of nipple position has also been shown to be moderately representative of overall cosmetic result[6]. BRA is a two dimensional measurement of nipple position and some cosmetic factors such as volume, shape or skin changes cannot be accurately assessed[11]. This is probably the reason why BRA shows a better cosmetic outcome when compared with subjective assessment by panel members. In this study only one (1%) patient was deemed to have a poor cosmetic outcome using BRA compared with 12 (10%) using panel assessment.

A criticism of the current study is that patients' perceptions of their own cosmetic outcome were not assessed. Previous studies have shown a significant correlation between patient satisfaction after breast-conserving surgery and their self-assessment of cosmesis[12, 13]. This study shows that there is need to find a reproducible method of cosmetic assessment which takes into account all the limitations of the methods currently used. More recently computer software like BCCT.core and Breast Analysing Tool have been developed and early results using these software are promising[14, 15]. There are various factors that are known to affect cosmesis following breast-conserving surgery. As expected larger percentage volume of excised breast tissue was associated with poorer cosmetic result. This was particularly evident from panel assessment. Such a relationship was less clear with BRA and ND. The effect of percentage volume of breast tissue excised and the outcome is consistent with a recent report that showed higher patient satisfaction if estimated percentage breast volume excised was < 10%[16]. Cosmetic outcome based on tumour location varies depending on the method of assessment used. BRA is adversely affected by tumour in the upper and outer quadrants of the breast, suggesting that surgery causes larger nipple deviation in this quadrant, while panel assessment gives poor scores for tumours located in inferior quadrant[2, 11]. In this study only 19% of patients had tumours located in the inner quadrant and the small number may explain why, no significant difference in cosmetic outcome was found. Tumour location or the number of operations performed did not appear to affect the cosmetic outcome in this study. The volume of breast tissue excised depends on tumour size. Since the majority of tumours in this study were small, the size of the tumour did not affect cosmetic outcome except when nipple deviation was used. This once again indicates that these three methods of assessment may be looking at different aspects of cosmesis.

In conclusion, cosmetic outcome following breast-conserving surgery is an important, measurable end point. However, the best method of assessment of cosmesis has not been devised[17]. Although, the objective methods are easier to apply and reproduce, they do not give a good assessment of global cosmetic results. Panel Assessment however, does appear to provide concordant results between different observers and may be a useful, simple measure of cosmetic assessment following breast-conserving surgery.

Competing interests
None Declared
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Review Article

Role of Chronic Bacterial and Viral Infections in Neurodegenerative, Neurobehavioural, Psychiatric, Autoimmune and Fatiguing Illnesses: Part 2

Garth L. Nicolson and Jörg Haier

ABSTRACT

Chronically ill patients with neurodegenerative and neurobehavioural and psychiatric diseases commonly have systemic and central nervous system bacterial and viral infections. In addition, other chronic illnesses where neurological manifestations are routinely found, such as fatiguing and autoimmune diseases, Lyme disease and Gulf War illnesses, also show systemic bacterial and viral infections that could be important in disease inception, progression or increasing the types/severities of signs and symptoms. Evidence of *Mycoplasma* species, *Chlamydia pneumoniae*, *Borrelia burgdorferi*, human herpesvirus-1, -6 and -7 and other bacterial and viral infections revealed high infection rates in the above illnesses that were not found in controls. Although the specific roles of chronic infections in various diseases and their pathogeneses have not been carefully determined, the data suggest that chronic bacterial and/or viral infections are common features of progressive chronic diseases.

ABBREVIATIONS

Ab Beta Amyloid; AD Alzheimer's Disease; ADHD Attention-Deficit Hyperactivity Disorder; ALS Amyotrophic Lateral Sclerosis; ASD Autism Spectrum Disorders; EBV Epstein-Barr Virus; CFS Chronic Fatigue Syndrome; CFS/ME Chronic Fatigue Syndrome/Myalgic Encephalomyopathy; CI Confidence Interval; CMV Cytomegalovirus; CSF Cerebrospinal Fluid; CNS Central Nervous System; ELISA Enzyme Linked Immunoabsorbant Assay; GS Guillain-Barré Syndrome; GWI Gulf War Illnesses; HHV Human Herpes Virus; HSV Herpes Simplex Virus; MDD Major Depressive Disorder; ME Myalgic Encephalomyelitis; MRI Magnetic Resonance Imaging; MS Multiple Sclerosis; OCD Obsessive-Compulsive Disorder; PANDAS Paediatric Autoimmune Neuropsychiatric Disorders Associated With Streptococci; PCR Polymerase Chain Reaction; PD Parkinson's Disease; QOL Quality Of Life; TS Tourette's Syndrome

Introduction

In the first part of this review we considered neurodegenerative and neurobehavioural diseases and the findings that these diseases commonly are associated with systemic and central nervous system bacterial and viral infections.[1] In this second part we continue with psychiatric diseases, autoimmune diseases, fatiguing illnesses, and other chronic diseases where chronic infections play an important role.

Psychiatric diseases

Borrelia-associated psychiatric disorders

In addition to neurologic and rheumatologic symptoms *Borrelia burgdorferi* has been associated with several psychiatric manifestations[2, 3] (see also below). Such infections can invade the central nervous system and may cause or mimic psychiatric disorders or cause a co-morbid condition. A broad range of psychiatric conditions have been associated with Lyme disease, including paranoia, dementia, schizophrenia, bipolar disorder, panic attacks, major depression, anorexia nervosa and obsessive-compulsive disorder.[4-7] For example, depressive states among patients with late Lyme disease are fairly common, ranging from 26% to 66%.[3] It is not known whether *B. burgdorferi* contributes to overall psychiatric morbidity, but undiagnosed chronic Lyme disease caused by this spirochete is considered a differential diagnosis in patients with certain psychiatric symptoms such as depressive symptoms, lack of concentration and fatigue.

The neuropsychiatric sequelae of chronic Lyme disease remains unclear. Studies were performed, some on large numbers of patients, to investigate whether a correlation exists between chronic Lyme disease (defined by seropositivity) and psychiatric disorders.[8-11] Interestingly, different results were reported on the association between *B. burgdorferi* infection and psychiatric morbidity.[8-11] For example, Hájek et al.[8] compared the prevalence of antibodies to *B. burgdorferi* in groups of psychiatric patients and healthy subjects. Among the matched pairs, 33% of the psychiatric patients and 19% of the healthy comparison subjects were seropositive. In contrast, Grabe et al.[11] did not find an association between *Borrelia* seropositivity and mental and physical complaints. In 926 consecutive psychiatric patients that were screened for antibodies and compared with 884 simultaneously recruited healthy subjects, seropositive psychiatric patients were found to be significantly younger than seronegative ones, and this was not found in the healthy controls.[10] However, none of the psychiatric diagnostic categories used in this study exhibited a stronger association with seropositivity.[10] These findings suggest a potential association between *B. burgdorferi* infection and psychiatric

morbidity, but fail to identify any specific clinical 'signature' of the infection. This might be due to the very low incidence in an endemic region (0.2%, CI 95% 0.0% to 1.1%) as demonstrated in 517 patients hospitalized for psychiatric diseases.[9]

In addition to serological data, clinical evidence for the association of psychiatric symptoms and post-Lyme disease has also been investigated. If mental and physical complaints in patients were assessed with the von Zerssen's complaint scale using multivariate analyses, the data revealed that definitions of seropositivity were not associated with increased mental or physical complaints.[11] In contrast, if the SF-36 was used to determine Quality of Life (QOL) in post-Lyme patients, the average SF-36 physical component summary (40±9, range 29-44) and mental component summary (39±14, range 23-46) of the QOL assessment were worse than the general USA population, and they could be significantly improved by anti-Lyme antibiotics (46% versus 18%, p=0.007).[5] Barr et al.[12] examined the relation between complaints of memory disturbance and measures of mood and memory functioning in 55 patients with serological evidence of late-stage Lyme borreliosis. There was a significant correlation between subjective memory ratings and self-reported depression (p<0.001) but not with objective memory performance, indicating memory disturbance in chronic Lyme patients. Using a structured psychiatric interview, the Positive and Negative Affect Schedule, the Lyme Symptom Checklist, and a battery of neuropsychological tests in 30 post-Lyme patients, participants did not appear to have an elevated incidence of psychiatric disorders or psychiatric history.[13] Their mood, however, was characterized by lowered levels of positive affect and typical levels of negative affect that were similar to affect patterns in individuals with chronic fatigue syndrome (CFS). Similarly, Hasset et al.[4, 7] reported on 240 consecutive post-Lyme patients who were screened for clinical psychiatric disorders, such as depression and anxiety. After adjusting for age and sex, these disorders were more common in symptomatic patients than in the comparison group (Odds Ratio=3.54, CI 95% 1.97-6.55, p<0.001), but personality disorders were comparable in both groups.

Although psychiatric co-morbidity and other psychological factors are prominent in post-Lyme patients, it remains uncertain whether these symptoms can be directly attributed to the chronic course of *Borrelia* infections or to other chronic illness-related factors.

Schizophrenia

Several microbes have been suspected as pathogenetic factors in schizophrenia, such as *Chlamydia species*, *toxoplasma*, and various viruses. For example, a number of studies have reported associations between *Toxoplasma gondii* infection and the risk of schizophrenia with an overall hazard ratio of 1.24.[14] In addition, chlamydial infections have been found in 40% of schizophrenic patients compared to 7% in healthy controls.[15] These infections represented the highest risk factor yet found to be associated with schizophrenia that was highly significant (Odds Ratio=9.43, p=1.39 x 10^{-10}), especially with *Chlamydophila psittaci* (Odds Ratio=24.39, p=2.81 x 10^{-7}). Interestingly, schizophrenic carriers of the HLA-A10 genotype were clearly the most often infected with *Chlamydia*, especially *C. psittaci* (Odds Ratio=50.00,p=8.03 x 10^{-5}), pointing to a genetically related susceptibility.[15] However, skepticism against the role of bacterial infection in schizophrenia was also fostered by the low impact of anti-infectious treatment on the course of disease progression in schizophrenia.[16]

Genetic backgrounds and viral infections and/or reactivations as well as cytokine-related pathomechanisms have also been proposed as causative for psychiatric disorders, such as schizophrenia. Specific genetic patterns of MICB polymorphism (MHC class I polypeptide-related sequence B, chromosome 6p21) were identified in patients seropositive for CMV and HSV-1.[17] Similar polymorphisms were found for the COMT Val158Met related to serological evidence of HSV-1 infections in individuals with bipolar disorder.[18] This serologic evidence of HSV-1 infection appeared to be associated with cognitive impairment in individuals with bipolar disorders[19] and was found to be an independent predictor of cognitive dysfunction in individuals with schizophrenia.[20] In addition, viral exposure during gestation has been described as a risk factor for schizophrenia. Offspring of mothers with serologic evidence of HSV-2 infection were at significantly increased risk for the development of psychoses (Odds Ratio=1.6; CI 95% 1.1-2.3). These results are consistent with a general model of risk resulting from enhanced maternal immune activation during pregnancy.[21]However, this was not confirmed in another study.[22] Similar contradictory results were observed in a small group of 8 patients with schizophrenia where reactivation of herpesviruses (HSV-1, CMV, EBV, varicella-zoster virus and human HHV-6) and other viruses (measles, rubella, mumps, influenzaA and B and Japanese encephalitis viruses) during acute onset or exacerbation of schizophrenia was investigated, but none of these viruses were detected in these patients.[23]Also, a search for HSV-1 or varicella zoster virus infection in postmortem brain tissue from schizophrenic patients did not reveal evidence of persistent CNS infections with these viruses.[24]

Schizophrenic patients show a number of cytokine changes that may be important in their condition. For example, differences in interleukin-2, -4 and –6, among other cytokines, have been seen in schizophrenic patients.[25-27] Often these changes in cytokines or cytokine receptors have been linked to associated genetic changes found in schizophrenia.[28-30] Monji et al.[31] recently reviewed the evidence for neuroinflammation, increases in pro-inflammatory cytokines and genetic changes in schizophrenia and concluded that these changes are closely linked to activation of microglia. Although the microglia

comprise only about 10% of the total brain cells, they respond rapidly to even minor pathological changes in the brain and may contribute to neurodegeneration through the production of pro-inflammatory cytokines and free radicals. CNS infections could also activate microglia and cause similar events.

Neuropsychiatric Movement Disorders

Giles de la Tourette's syndrome (TS) is a neurological condition that usually begins in childhood and results in involuntary sounds or words (vocal tics) and body movements (movement tics). An association between infection and TS has been repeatedly described.[32] Abrupt onset of the disease, usually after infection, was noted in up to 11% of these patients.[33-34] A role for streptococcal infections (PANDAS, see below) as causative or mediating agent in TS was established several years ago.[35] Additionally, the involvement of other infectious agents, such as *B. Burgdorferi* or *M. pneumoniae,* has been described in case reports and small studies. For example, comparing 29 TS patients with 29 controls revealed significantly elevated serological titers in TS patients (59% versus 3%). This higher proportion of increased serum titers, especially IgA titers, suggested a putative role for *M. pneumoniae* in a subgroup of patients with TS.[36] In predisposed persons, infection with various agents including *M. pneumoniae* should be considered as at least an aggravating factor, but an autoimmune reaction has to be taken into account in TS patients. In addition, co-infections with toxoplasmosis have been described in a few case reports of obsessive-compulsive disorder (OCD).[37] As mentioned above, streptococcal infections are likely to play a pivotal role in these syndromes.[35]

The pathogenic mechanism may be secondary to an activation of the immune system, resulting in an autoimmune response. This will be discussed in the next section.

Autoimmune Diseases

Infections are associated with various autoimmune conditions.[38-40] Autoimmunity can occur when infections like cell-wall-deficient bacteria are released from cells containing parts of cell membranes that are then seen as part of a bacterial antigen complex, or bacteria can synthesize mimicry antigens (glycolipids, glycoproteins or polysaccharides) that are similar enough in structure (molecular mimicry) to stimulate autoimmune responses against similar host antigens. Alternatively, viral infections can weaken or kill cells and thus release cellular antigens, which can stimulate autoimmune responses, or they can incorporate molecules like gangliosides into their structures.

In addition to molecular mimicry, autoimmunity involves several other complex relationships within the host, including inflammatory cytokines, Toll-like receptor signalling, stress or shock proteins, nitric oxide and other stress-related free radicals, among other changes that together result in autoimmune disease.[38, 39]

Guillain-Barré syndrome

Guillain-Barré syndrome (GB) is a demyelinating autoimmune neuropathy often associated with bacterial infections.[40] Symptoms include pain, muscle weakness, numbness or tingling in the arms, legs and face, trouble speaking, chewing and swallowing. Of the types of infections found in GB, *Campylobacter jejuni*, *Mycoplasma pneumonia* and *Haemophilus influenzae* are often found.[39] For example, Taylor et al.[41] found serological evidence of *C. jejuni* in 5 of 7 patients with GB and other motor neuropathies, and Gregson et al.[42] found anti-ganglioside GM_1 antibodies that cross-reacted with *C. jejuni* liposaccharide isolates. When infections were examined in GB cases in India, Gorthi et al.[43] found that 35% and 50% of GB patients had serological evidence of *C. jejuni* and *M. penumoniae* infections, respectively, while one-third of cases showed evidence of both infections. In Japan Mori et al.[44] found that 13% of GB patients had antibodies against *Haemophilus influenzae* . Autoantibodies stimulated by infections found in GB patients can cross-react with nerve cell gangliosides (anti-GM_1, anti-GM_{1b}, anti-GD_{1a}, among others), and these are thought to be important in the pathogenesis of GB.[45] Indeed, injection of *C. jejuni* lipo-oligosaccharide into rabbits induces anti-gangliosides and a neuropathy that resembles acute motor axonal neuropathy.[46]

Viruses have also been found to be associated with GB.[40] Examples are: CMV,[47] HIV,[48] herpes simplex virus,[49] West Nile virus,[50] and HHV-6.[51]

Paediatric autoimmune neuropsychiatric disorders associated with Streptococci ('PANDAS')

Streptococcal infections in children are usually benign and self-limited. In a small percentage of children, however, prominent neurologic and/or psychiatric sequelae can occur. Post-streptococcal basal ganglia dysfunction has been reported with various manifestations, all of which fall into a relatively well-defined symptom complex or syndrome called paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS).[52]

Evidence from past studies indicates that adults and children with a symptom course consistent with PANDAS experience subtle neuropsychological deficits similar to those of primary psychiatric diagnosis of OCD and TS.[53] PANDAS are now considered as a well-defined syndrome in which tics (motor and/or vocal) and/or OCD are consistently exacerbated in temporal correlation to a group A beta-hemolytic streptococcal infection. However, the pathological relationship between OCD or tics/TS in childhood to antecedent *group A Streptococci* is still not fully understood.[52]

In an epidemiological investigation Leslie et al.[54] assessed whether antecedent streptococcal infection(s) increase the risk of subsequent diagnosis of OCD, TS, other tic disorders, attention-deficit hyperactivity disorder (ADHD) or major depressive disorder (MDD). Children with newly diagnosed OCD, TS, or tic disorder were more likely than controls to have had a diagnosis of streptococcal infection in the previous year (Odds Ratio=1.54, CI 95% 1.29-2.15). Previous streptococcal infection was also associated with incident diagnoses of ADHD (Odds Ratio=1.20, CI 95% 1.06-1.35) and MDD (Odds Ratio=1.63, CI 95% 1.12-2.30).[54] Similar results were found in a retrospective, cross-sectional, observational study of 176 children and adolescents with tics, TS, and related problems.[55] In a case-control study of children 4 to 13 years old patients with OCD, TS, or tic these disorders were more likely than controls to have had prior streptococcal infection (Odds Ratio=2.22; CI 95% 1.05-4.69) in the 3 months before onset date. The risk was higher among children with multiple streptococcal infections within 12 months (Odds Ratio=3.10; CI 95% 1.77-8.96).[56] Having multiple infections with *group A beta-hemolytic Streptococcus* within a 12-month period was associated with an increased risk for TS (Odds Ratio=13.6; CI 95% 1.93-51.0). Similar results were found in patients with typical symptoms of Tourette's syndrome.[57] The frequency of elevated anti-streptolysin O titers was also significantly higher (p=0.04) in patients with attention-deficit hyperactivity disorder (64%) than in a control group (34%).[58]

Sydenham's chorea is one manifestation of post-streptococcal neuropsychiatric movement disorders. A pathogenic similarity between Sydenham's chorea, TS and other PANDAS has been suggested since some patients can present with one diagnosis and then evolve with other neuropsychiatric conditions.[59] These observations support a role of group A streptococcal infection and basal ganglia autoimmunity. Anti-basal ganglia antibodies that are associated with serologic evidence of recent streptococcal infection were found as potential diagnostic markers for this group of disorders, which includes Sydenham's chorea as the prototype.[60]

However, contradictory results were also reported.[61] For example, an association between symptom exacerbations and new *group A beta-hemolytic streptococcus* infections among 47 paediatric patients with TS and/or OCD was not observed.[59] In addition, the failure of immune markers for streptococcal infections to correlate with clinical exacerbations in a small study of children with paediatric autoimmune neuropsychiatric disorders raised concerns about the viability of autoimmunity as a pathophysiological mechanism in these syndromes.[62] However, in a second study the same group reported that patients who fit published criteria for paediatric autoimmune neuropsychiatric disorders associated with streptococcal infections represented a subgroup of those with chronic tic disorders and OCD. These patients may be vulnerable to *group A beta-hemolytic Streptococcus* infection as a precipitant of neuropsychiatric symptom exacerbations. [63]

Taken together, these findings provide epidemiologic evidence that some paediatric-onset neuropsychiatric disorders, including OCD, tic disorders, ADHD, and MDD, may be, at least partially, related to prior streptococcal infections. *Group A beta-hemolytic Streptococcus* infections are likely not the only event associated with symptom exacerbations for PANDAS patients, but they appear to play a role at least in a subgroup of these children. A potential genetic susceptibility for these post-infectious complexes has been recently proposed.[64]

The recent recognition that these paediatric neurobehavioural syndromes have infectious and/or immunologic triggers has pointed to important new avenues for their management.

Fatiguing illnesses

Chronic fatigue syndrome/myalgic encephalomyelitis

Chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) is a fatiguing illness characterised by unexplained, persistent long-term disabling fatigue plus additional signs and symptoms, including neurophysiological symptoms.[65] Brain imaging studies have shown that CFS/ME patients are dysfunctional in their ventral anterior cingulate cortex, and they also have other brain MRI abnormalities.[66, 67] In addition, CFS/ME patients also have immunological and inflammation abnormalities, such as alternations in natural killer cell function[68, 69] and cytokine profiles.[70, 71] In addition, the hypothalamo-pituitary-adrenal axis, which plays a major role in stress responses, appears to be altered in CFS/ME.[72]

Most, if not all, CFS/ME patients have multiple chronic bacterial and viral infections.[73-80] For example, when patients were examined for evidence of multiple, systemic bacterial and viral infections, the Odds Ratio for this was found to be 18 (CI 95% 8.5-37.9, p< 0.001).[75] In this study CFS/ME patients had a high prevalence of one of four *Mycoplasma* species (Odds Ratio=13.8, CI 95% 5.8-32.9, p< 0.001) and often showed evidence of co-infections with different *Mycoplasma* species, *C. pneumoniae* (Odds Ratio=8.6, CI 95% 1.0-71.1, p< 0.01) and HHV-6 (Odds Ratio=4.5, CI 95% 2.0-10.2, p< 0.001).[75] In a separate study the presence of these infections was also related to the number and severity of signs and symptoms in CFS/ME patients, including neurological symptoms.[77] Similarly, Vojdani et al.[76] found *Mycoplasma* species in a majority of CFS/ME patients, but this has not been seen in all studies.[81] Interestingly, when European CFS/ME patients were examined for various *Mycoplasma* species, the most common species found was *M. hominis*,[82] whereas in North America the most common species found was *M. pneumoniae*,[75, 77] indicating possible regional differences in the types of infections in CFS/ME patients. In addition to Mycoplasma species, CFS/ME patients

are also often infected with *B. burgdorferi*,[80] and as mentioned above, *C. pneumoniae*.[75, 77, 83]

Other infections are also found in CFS/ME patients, such as viral infections: CMV,[84] parvovirus B19,[78] enterovirus[79] and HHV-6.[75, 77, 85-88] For example, Ablashi et al.[88] found that 54% of CFS/ME patients had antibodies against HHV-6 early protein, compared to 8% of controls. Similarly, Patnaik et al.[86] found that 77% of CFS/ME patients were positive for HHV-6 early antigen IgG or IgM antibodies, whereas only 12% of control subjects had IgG or IgM antibodies to HHV-6 early antigen. Recently a new retrovirus, XMRV, was found in mononuclear blood cells of 67% of 101 chronic fatigue syndrome patients compared to only 3.7% of healthy controls. Cell culture experiments determined that the patient-derived virus was infectious and could possibly be transmitted.[89]

Gulf War illnesses

GWI is a syndrome similar to CFS/ME.[90] In most GWI patients the variable incubation time, ranging from months to years after presumed exposure, the cyclic nature of the relapsing fevers and the other chronic signs and symptoms, and their subsequent appearance in immediate family members, are consistent with an infectious process.[90, 91] GWI patients were exposed to a variety of toxic materials including chemicals, radiochemicals and biologicals so not all patients are likely to have infections as their main clinical problem. Neurological symptoms are common in GWI cases.[90] Baumzweiger and Grove[92] have described GWI as neuro-immune disorder that involves the central, peripheral and autonomic nervous systems as well as the immune system. They attribute a major source of the illness to brainstem damage and central, peripheral and cranial nerve dysfunction from demyelination. They found GWI patients have muscle spasms, memory and attention deficits, ataxia and increased muscle tone.[92]

Bacterial infections were a common finding in many GWI patients.[90] Mycoplasmal infections were found in about one-half of GWI patients, and more than 80% of these cases were PCR positive for *M. fermentans*.[90, 91, 93-95] In studies of over 1,500 U.S. and British veterans with GWI, approximately 45% of GWI patients have PCR evidence of such infections, compared to 6% in the non-deployed, healthy population. Other infections found in GWI cases at much lower incidence were *Y. pestis*, *Coxiella burnetii* and *Brucella* species.[90]

When we examined the immediate family members of veterans with GWI who became sick only after the veteran returned to the home, we found that >53% had positive tests for mycoplasmal infections and showed symptoms of CFS/ME. Among the CFS/ME-symptomatic family members, most (>80%) had the same *Mycoplasma fermentans* infection as the GWI patients compared to the few non-symptomatic family members who had similar infections (Odds Ratio=16.9, CI 95% 6.0-47.6, $p<0.001$).[91] In contrast, in the few non-symptomatic family members that tested *Mycoplasma*-positive, the *Mycoplasma* species were often different from the species found in the Gulf War Illness patients (*M. fermentans*). The most sensible conclusion is that veterans came home with *M. fermentans* infections and then transmitted these infections to immediate family members.[91]

Some other infectious diseases with neurological aspects

Lyme Disease

Lyme disease is caused by a tick bite and the entry of the spiral-shaped spirochete *B. burgdorferi* as well as other co-infections.[96] Lyme disease is the most common tick-borne disease in North America. After incubation for a few days to a month, the *Borrelia* spirochete and co-infections migrate through the subcutaneous tissues into the lymph and blood where they can travel to near and distant host sites, including the central nervous system.[3, 97-99] Transplacental transmission of *B. burgdorferi* and co-infections can occur in pregnant animals, including humans, and blood-borne transmission to humans by blood transfusion is likely but unproven. The tick-borne co-infections associated with Lyme disease can and usually do appear clinically at the same time, complicating clinical dignoses.[100]

Lyme disease signs and symptoms eventually overlap with the signs and symptoms of other chronic illnesses, and patients are often diagnosed with illnesses like CFS/ME, chronic arthritis or a neurological disease.[80, 97-100] About one-third of cases with Lyme disease start with the appearance of a round, red, bulls-eye skin rash (*erythema migrans)* at the site of the tick bite, usually within 3-30 days.[100] Within days to weeks mild flu-like symptoms can occur that include shaking chills, intermittent fevers and local lymph node swelling. After this localised phase, which can last weeks to months, the infection can spread to other sites resulting in disseminated disease. In the disseminated (late) phase patients present with malaise, fatigue, fever and chills, headaches, stiff neck, facial nerve palsies (Bell's palsy) and muscle and joint pain, and other signs and symptoms.[100-104]

The disseminated (late) phase of Lyme disease is a chronic, persistent disease with ophthalmic, cardiac, musculoskeletal, central nervous system and internal organ invasion. When it involves the central and peripheral nervous systems, it is often termed neuroborreliosis.[100, 104] At this late stage, arthritis, neurological impairment with memory and cognitive loss, cardiac problems (such as myocarditis, endocarditis causing palpitations, pain, bradycardia, hypertension) and severe chronic fatigue are usually apparent.[80, 100-102] The signs and symptoms of the chronic (late) phase of the disease usually overlap with other chronic conditions, such as CFS/ME, chronic arthritis, as well as neurodegenerative diseases, causing confusion in the diagnosis and treatment of the chronic phase in patients with Lyme Disease.[80, 97, 100, 105] Patients with late stage neuroborreliosis exhibit neuropathologic and

neuropsychiatric disease similar to some of the neurodegenerative diseases discussed in previous sections.[1]

Diagnostic laboratory testing for Lyme disease at various clinical stages is not fool-proof, and experts often use a checklist of signs and symptoms and potential exposures, along with multiple laboratory tests to diagnose Lyme disease.[104] The laboratory tests include serology, Western blot analysis of *B.burgdorferi* associated bands, PCR analysis of blood and the nonspecific decrease in CD-57 natural killer cells. Unfortunately, similar to other intracellular bacteria,*Borrelia* spirochetes are not always released into the blood circulation or other body fluids, making the very sensitive PCR method less than reliable for diagnosing Lyme *Borrelia* with blood samples. Lebech and Hansen[106] found that only 40% of cerebrospinal fluid samples from patients with Lyme neuroborreliosis were positive for *B. burgdorferi* by PCR.

Co-infections in Lyme disease are important but, in general, have not received the attention that *B. burgdorferi* attracts. Some of the Lyme Disease co-infections on their own, such as *M. fermentans*, have been shown to produce signs and symptoms comparable to *B. burgdorferi* infections.[80, 102]

The most common co-infections found in Lyme disease are species of *Mycoplasma*, mostly *M. fermentans,* present in a majority of cases.[80, 103, 107] In some cases multiple mycoplasmal infections are present in patients with Lyme disease,[80]while other common co-infections include *Ehrlichia* species, *Bartonella* species and *Babesia* species. Such co-infections are present in 10-40% of cases.[103, 104, 108-112] *Ehrlichia* and *Bartonella* species are usually found along with *Mycoplasma*species in Lyme disease.[94, 98, 108-111] *Bartonella* species, such as *B. henselae*,[111] which also causes cat-scratch disease,[113]are often found in neurological cases of Lyme disease.[100, 111]

Protozoan co-infections have been found with *B. burgdorferi*, such as intracellular *Babesia* species.[100, 108, 109, 112, 114]The combination of *Borrelia*, *Mycoplasma* and *Babesia* infections can be lethal in some patients, and ~7% of patients can have disseminated intravascular coagulation, acute respiratory distress syndrome and heart failure.[109]

Brucellosis

Brucellosis is a nonspecific clinical condition characterized by intracellular *Brucella* species infection.[115] Approximately 40% of patients with *Brucella* spp. infections have a systemic, multi-organ chronic form of brucellosis that is similar to CFS/ME in its multi-organ signs and symptoms.[115, 116] *Brucella* infections can invade the central nervous system and cause neurological symptoms.[117]

Brucella species cause infections in animals, and often humans get the infections from prolonged contact with infected animals. Thus these bacteria are zoonotic, they are capable of being transmitted from animals to humans. Although there are at least eight species of *Brucella* that are pathogenic, only *B. melitensis, B. abortus, B. suis* and *B. canis* have been reported to be pathogenic in humans.[116]

When CFS/ME patients were examined for the presence of *Brucella* spp. infections, approximately 10% showed evidence by PCR of *Brucella* spp. infections (Odds Ratio=8.2, CI 95% 1-66, $p<0.01$).[118] Interestingly, urban CFS/ME patients with *Brucella* infections were not as prevalent as rural patients with *Brucella* infections (Odds Ratio=5.5, CI 95% 3-23.5, $p<0.02$), while control subjects had very low (1.4%) rates of infection. Co-infections with *Mycoplasma*species were also found in *Brucella*-positive CFS/ME patients.[118]

Final comments to part 2

The progression, and in some cases, the inception of many chronic diseases are probably elicited by various bacterial and viral infections.[1, 39, 40, 119] Even if infections are not directly involved in the pathogenesis of these diseases, patients with chronic conditions are at risk of a variety of opportunistic infections that could result in co-morbid conditions or promote disease progression. Infections can complicate diagnosis and treatment, and patients with late-stage disease with complex neurological manifestations, such as meningitis, encephalitis, peripheral neuropathy, psychiatric conditions, or with other signs and symptoms could have infections that are not recognized or treated.

Patients with chronic diseases are particularly difficult to treat using single modality approaches, and this is particularly true for patients who also have multiple chronic infections.[103, 109] The multi-focal nature of chronic diseases and the fact that often treatments are given to suppress signs and symptoms, rather than treat causes of the disease or its progression, have resulted in incomplete or ineffective treatments. On the other hand, even if the causes of chronic diseases are known, by the time therapeutic intervention is undertaken, it may be entirely too late to use approaches that should work on the disease if chronic infections were not present. Moreover, if complex, chronic infections are ignored or left untreated, recovery may be difficult, if not impossible to achieve.

At the moment the evidence that particular or specific types of infections are responsible for the inception or pathogenesis of chronic diseases is inconclusive.[119] One of the problems that arises in trying to prove this hypothesis is that not all patients appear to have similar chronic infections. Some individuals can harbour chronic infections without any observable signs or symptoms. Although the incidence of chronic infections of the types discussed in this review in symptom-free individuals is generally very low, usually only a few percent,[74-76, 120] that does not prove that they are important in pathogenesis. Since patients with chronic diseases have been identified that do not have easily diagnosed chronic infections, most researchers have

concluded that infections are not involved in the pathogenesis of chronic diseases. Unfortunately, the tools available to find chronic infections are not optimal, and many patients are likely go undiagnosed with chronic infections for purely technical reasons.[1, 119-121]

In the history of medicine animal models of disease have provided useful information that could not be obtained through clinical studies alone. Indeed, the field of chronic diseases could benefit from the greater use of relevant animal models. We suggest that to be useful, the pathogenesis of the animal models of disease must be similar to the pathogenesis of human disease and the animal models must have a similar response to therapy as humans. Thus such models are only relevant if they closely mimic human disease and its response to treatment. For example, the infection of non-human primates with neuropathologic microorganisms, such as *Mycoplasma fermentans*, resulted in brain infections and fatal diseases with clinically typical neurological signs and symptoms.[122] These primates also respond to therapies that have been used successfully to treat humans.[93, 123] Thus this particular model may be useful if it can be reprocucibly infected with specific microorganisms and later develop neurological signs and symptoms that closely mimic chronic human neurological diseases. Future efforts to determine the relationship between specific infections and the pathogenesis of various chronic diseases may well depend on the further development of relevant animal models.

Competing Interests
None declared
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Review Article

Chemical and physical restraint use in the older person

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Abstract
A restraint is a device or medication that is used to restrict a patient's voluntary movement. Reported prevalence of physical restraint varies from 7.4% to 17% use in acute care hospitals up to 37% in long term care in the United States. Prevalence of 34% psychotropic drug use in long term care facilities in the United States has been reported; but use is decreasing, probably due to regulation. Use of restraints often has an effect opposite of the intended purpose, which is to protect the patient. The risk of using a restraint must be weighed against the risk of not using one, and informed consent with proxy decision makers should occur. Comprehensive nursing assessment of problem behaviours, a physician order when instituting restraints, and documentation of failure of alternatives to restraint is required. Ignorance about the dangers of restraint use results in a sincere, but misguided, belief that one is acting in the patient's best interest.Steps can be taken to reduce restraints before the need for restraints arises, when the need for restraints finally does arise, and while the use of restraints is ongoing.

Keywords
physical restraint, chemical restraint, aged care, antipsychotic agents, therapeutic use, psychotropic agents, treatment outcome, regulations

Definition of restraint: a device or medication that is used to restrict a patient's voluntary movement.
Prevalence of physical restraints: up to 17% in acute care settings.
Prevalence of chemical restraints: up to 34% psychotropic drug use in long term care facilities.
Complications of restraints: include documented falls, decubitus ulcers, fractures, and death.
Regulations: require documentation of indications plus failure of alternatives by a licensed professional.
Prevention of removal of life sustaining treatment: is a relatively clear indication for restraints.
Informed consent: including consideration of risks, benefits, and alternatives is necessary in all cases.
Barrier to reducing restraints: a misguided belief that, by use, one is preventing patient injury.
Steps can be taken to limit their use: including an analysis of behaviours precipitating their use.

Case study

A 79 year old female nursing home resident with frontotemporal dementia and spinal stenosis has a chronic indwelling catheter for cauda equina syndrome and neurogenic bladder. Attempts to remove the catheter and begin straight catheterization every shift were met by the patient becoming combative with the staff. Replacing the catheter led to repeated episodes of the patient pulling out the catheter. The patient lacks decision making capacity to weigh the risks, benefits, and alternatives; but she clearly doesn't like having a catheter in. The attending physician instituted wrist restraints pending a team meeting. Unfortunately, attempts by the patient to get free led to dislocation of both shoulders and discharge to the hospital.

Introduction

A restraint is any device or medication used to restrict a patient's movement. In the intensive care unit, for example, soft wrist restraints may be used to prevent a patient from removing a precisely placed endotracheal tube. A lap belt intended to prevent an individual from falling from a wheelchair in a nursing home is a restraint if the patient is unable to readily undo the latch.1 In the case study above of a catheterized, demented patient, if medication is used to prevent the patient from striking out at staff when performing or maintaining catheterization, then the medication is considered a restraint.

There is little data on efficacy and benefits of restraints[1]. Even when the indication to use a restraint is relatively clear, the outcome is often opposite of the intention. Consider that restraints used for keeping patients from pulling out their endotracheal tubes are themselves associated with unplanned self- extubation[2]. Complications of restraints can be serious including death resulting from medications or devices[3,4]. Use of restraints should be reserved for documented indications, should be time limited, and there should be frequent re-evaluation of their indications, effectiveness, and side effects in each patient. Lack of a Food and Drug Administration (FDA) approved indication for use of medications as restraints in agitated, aggressive, demented patients has led to recommendations that medications in these situations be used only after informed consent with proxy decision makers[5]. Medical, environmental, and patient specific factors can be root causes of potentially injurious behavior to self or others as in the case study above. To ensure consideration and possible

amelioration of these underlying causes, the Center for Medicare and Medicaid Services (CMS) in 2006 required face to face medical and behavioral evaluation of a patient within one hour after restraints are instituted by a physician (licensed independent practitioner). As a result of controversy surrounding this rule, clarification of that rule in 2007 allowed for a registered nurse or physician assistant to perform the evaluation provided that the physician is notified as soon as possible[6] . In depth situational analysis of the circumstances surrounding the use of restraints in individual cases as well as education of the patient, family, and caregivers may lead to the use of less restrictive alternatives[7].

Frequency of restraint use

Frequency of restraint use depends on the setting, the type of restraint, and the country where restraint use is being studied. In the acute care hospital setting, reported physical restraint use was 7.4% to 17%.a decade ago[8].Two decades ago, in long term care facilities prevalence was reported as 28%-37%.[9] . There has been a steady decline over the past several decades coincident with regulation such that, according to the Department of Health and Human Services, it is down to about 5% since newer CMS rules went into effect in 2007. In contrast, some European nursing homes still report physical restraint use from 26% to 56%[10,11].

Chemical restraint is slightly more prevalent than physical restraint with a prevalence of up to 34% in long term care facilities in the US prior to regulations[12].There is some indication that prevalence may be decreasing, some say markedly, perhaps as a result of government regulation[13,12] .Interestingly, one case-control study of more than 71,000 nursing home patients in four states showed that patients in Alzheimer special care units were no less likely to be physically restrained compared to traditional units. Furthermore, they were more likely to receive psychotropic medication[14].

Complications of restraint use

The use of chemical and physical restraints is associated with an increase in confusion, falls, decubitus ulcers, and length of stay[15,16]. Increase in ADL dependence, walking dependence, and reduced cognitive function from baseline has also been reported[17]. Use of restraints often has an effect opposite the intended purpose of protecting the patient, especially when the intent is prevention of falls[18]. Physical restraints have even caused patient deaths. These deaths are typically due to asphyxia when a patient, attempting to become free of the restraint, becomes caught in a position that restricts breathing[4,19].

Antipsychotic medications may be used as restraints in elderly patients with delirium or dementia who become combative and endanger themselves and others; however, there is no FDA approval for these drugs for this use[5]. In a meta-analysis, an increased relative risk of mortality of 1.6 to 1.7 in the elderly prompted the FDA to mandate a "black box" label on atypical antipsychotic medications stating that they are not approved for use in the behavioral manifestations of dementia[20]. Other research suggests that conventional antipsychotics are just as likely to cause death, if not more so[3]. Forensic research also links antipsychotic medication and patient deaths[21]. The reported relative risk of falls from these drugs is 1.7[22]. Given the risks, if antipsychotic medications are used at all, they need to be prescribed as part of a documented informed-consent process. Education of patients, families of patients, and facility staff about the harms of restraints is a good first step in a plan to avoid or eliminate their use. Over the past several decades, regulations have arisen in the United States because of complications of restraints and a lack of clear evidence supporting their use.

The regulatory environment in the United States

The Omnibus Budget Reconciliation Act of 1987 (OBRA 87) resulted in regulations that specify the resident's right to be free of the use of restraints in nursing homes when used for the purpose of discipline or convenience and when not required to treat the resident's medical symptoms[23,24]. OBRA87 related regulations also specified that uncooperativeness, restlessness, wandering, or unsociability were not sufficient reasons to justify the use of antipsychotic medications. If delirium or dementia with psychotic features were to be used as indications, then the nature and frequency of the behavior that endangered the resident themselves, endangered others, or interfered with the staff's ability to provide care would need to be clearly documented[24]. Comprehensive nursing assessment of problem behaviors, a physician order before or immediately after instituting a restraint, and documentation of the failure of alternatives to restraint are required before the use of a restraint is permitted. The restraint must be used for a specific purpose and for a specified time, after which reevaluation is necessary.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) instituted similar guidelines that apply to any hospital or rehabilitation facility location where a restraint is used for physical restriction for behavioral reasons[25]. In response to the 1999 Institute of Medicine report, To Err is Human, JCAHO focused on improving reporting of sentinel events to increase awareness of serious medical errors. Not all sentinel events are medical errors, but they imply risk for errors as noted in the revised 2007 JCAHO sentinel event definition: A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof[6]. The JCAHO recommends risk reduction strategies that include eliminating the use of inappropriate or unsafe restraints. The recommendations for restraint reduction are prioritized along with items like eliminating wrong site surgery, reducing post-operative complications, and reducing the risk of intravenous infusion pump errors[6]. It is clear that JCAHO considers placing

restraints as a sentinel event to be monitored and reported. CMS and JCAHO have worked to align hospital and nursing home quality assurance efforts especially with respect to the standard concerning face to face evaluation of a patient within one hour of the institution of restraints. They held ongoing discussions that resulted in revised standards for the use of restraints in 2009[26]. Among the agreed upon standards are: policies and procedures for safe techniques for restraint, face to face evaluation by a physician or other authorized licensed independent practitioner within one hour of the institution of the restraint, written modification of the patient's care plan, no standing orders or prn use of restraints, use of restraints only when less restrictive interventions are ineffective, use of the least restrictive restraint that protects the safety of the patient, renewal of the order for a time period not to exceed four hours for an adult, restraint free periods, physician or licensed independent practitioner daily evaluation of the patient before re-ordering restraint, continuous monitoring, and documentation of strategies to identify environmental or patient specific triggers of the target behavior. The one hour face to face evaluation may be accomplished by a registered nurse provided that the attending physician is notified as soon as possible[26].

Indications for use of restraints

The risk of using a restraint must be weighed against the risk of not using one when physical restriction of activity is necessary to continue life-sustaining treatments such as mechanical ventilation, artificial feeding, or fluid resuscitation. Every attempt should be made to allow earlier weaning from these treatments, thereby rendering the restraint unnecessary. Even in cases where the indication is relatively clear, the risks, benefits, and alternatives must be weighed (see Figure). In an emergency, when it is necessary to get a licensed provider's order for a restraint to prevent a patient from disrupting lifesaving therapy or to keep a patient from injuring others, an analysis of what may be precipitating the episode is essential. Are environmental factors such as noise or lighting triggering the behavior? Are patient factors such as pain, constipation, dysuria, or poor vision or hearing triggering the disruptive behavior? Is there an acute medical illness? Is polypharmacy contributing? Psychotropic drugs and drugs with anticholinergic activity are common culprits. Patient, staff, family, and other health care providers need to be queried.

One must guard against perceiving the continued need for life-sustaining treatment and the use of restraints as being independent factors, because that misconception can lead to a vicious cycle. For example, a patient who has persistent delirium from polypharmacy and needs artificial nutrition and hydration which perpetuates the need for continued chemical and physical restraints. Correcting the polypharmacy and the restraint as a potential cause of the delirium can break the cycle. When restraints are indicated, one must use the least-restrictive restraint to accomplish what is needed for the shortest period of time. Restraint-free periods and periodic reassessments are absolutely required.

A weaker indication is the use of restraints to prevent patient self-injury when the danger is not imminent. Such an indication exists when a patient repeatedly attempts unsafe ambulation without assistance or when he or she cannot safely ambulate early in the process of rehabilitation from deconditioning or after surgery. In these cases, weighing the risks and benefits of the restraint is more difficult than when considering restraints to maintain life-sustaining treatment.

Even more difficult to justify is the use of restraints to restrict movement to provide nonurgent care. An example might be a patient who repeatedly removes an occlusive dressing for an early decubitus ulcer. In these cases, it is more fruitful to use alternatives to restraints. For example, considering alternatives to a urinary catheter is more important than documenting that restraints are indicated to keep the patient from pulling it out.

If used, the specific indication, time limit, and plan for ongoing reevaluation of the restraint must be clearly documented. Effectiveness and adverse effects must be monitored. Restraint-free periods are also mandatory. The same is true for chemical restraints. Periodic trials of dosage reduction and outcome are mandatory.

Barriers to reducing the use of restraints

Perceived barriers to reducing restraints can be thought of as opportunities to build relationships between patients, physicians, staff, patients' families, and facility leaders. A legitimate fear of patient injury, especially when the patient is unable to make his or her own decisions, is usually the root motivation to use restraints. Ignorance about the dangers of restraint use results in a sincere, but misguided, belief that one is acting in the patient's best interest[27]. Attempts to educate physicians, patients, and staff may not have been made. These barriers are opportunities for the community to work together in creative partnerships to solve these problems. Even in communities where there are no educational institutions, there are opportunities for educational leadership among physician, nursing, and other staff. Conversely, lack of commitment to reducing restraints by institutional leaders will tend to reinforce the preexisting barriers. Regulatory intervention has been a key part of gaining the commitment of institutional leadership when other opportunities were not seized. On the other hand, competing regulatory priorities such as viewing a serious fall injury as a 'never event' and simultaneously viewing institution of a restraint as a sentinel event may lead to reduced mobility of the patient[18]. An example of this would be the use of a lap belt with a patient-triggered release. The patient may technically be able to release the belt, but the restricted mobility may lead to deconditioning and an even higher fall risk when the patient leaves the hospital. In the process of preventing the serious fall injury or 'never event' there is, even at the regulatory level,

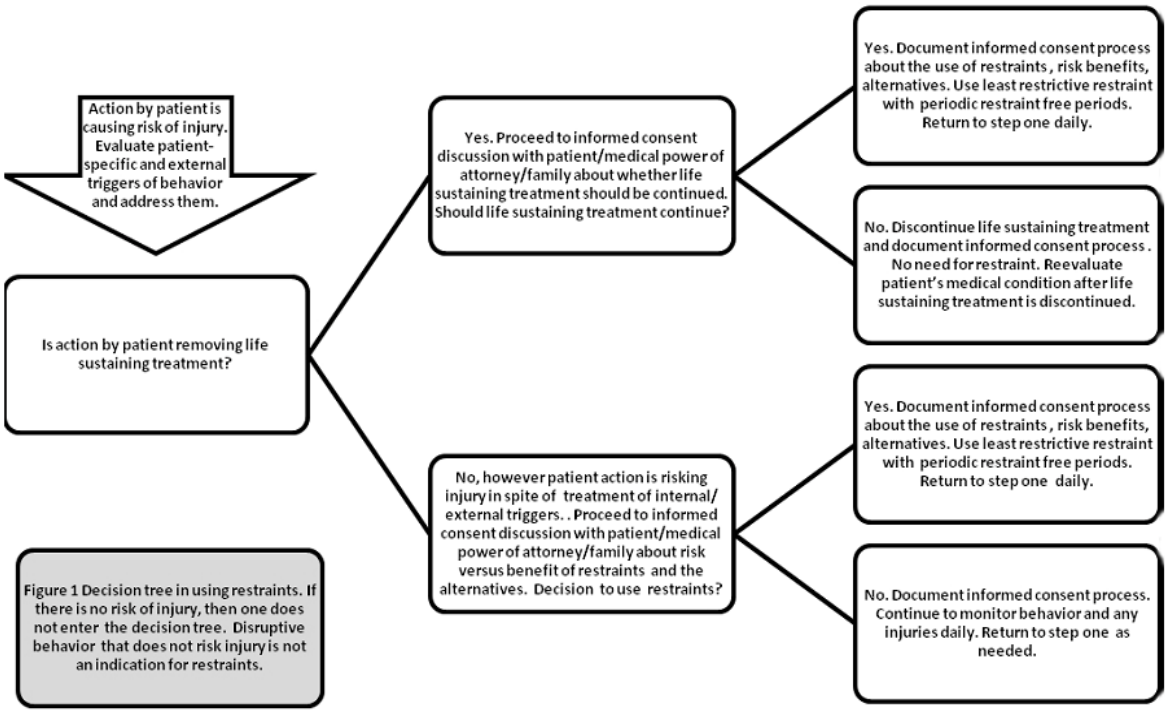

Figure 1 Decision tree in using restraints

intervention that may not be in the patient's best interest. These good intentions are, again, a barrier to the reduction of the use of restraints and an opportunity for physician leadership in systems based care collaboration. Physician leadership probably needs to extend beyond educational efforts. Evidence suggests education may be necessary but not sufficient to reduce the use of restraints[10].

Reducing the use of restraints

Steps can be taken to reduce the use of restraints before the need for them arises, when the need for restraints finally does arise, and while their use is ongoing.

Programs to prevent delirium, falls in high-risk patients, and polypharmacy are all examples of interventions that may prevent the need for restraints in the first place. Attention to adequate pain control, bowel function, bladder function, sleep, noise reduction, and lighting may all contribute to a restraint-free facility.

When a restraint is deemed necessary, a sentinel event has occurred. Attempts to troubleshoot the precipitating factors must follow. Acute illness such as infection, cardiac, or respiratory illness must be considered when a patient begins to demonstrate falls or begins to remove life-sustaining equipment. Highly individualized assessment of the patient often requires input from physical therapy, occupational therapy, social work, nursing, pharmacy, and family. If root causes are determined and corrected, the need for restraints can be ameliorated and alternatives can be instituted.

The least restrictive alternative should be implemented when needed. For example, a lowered bed height with padding on the floor can be used for a patient who is at risk for falls out of bed in contrast to the use of bedrails for that purpose. Another example is the use of a lap belt with a Velcro release as opposed to a vest restraint without a release. A third example is the use of a deck of cards or a lump of modeling clay to keep the patient involved in an alternative activity to the target behavior that may be endangering the patient or staff. Alternatives to the use of restraints need to be considered both when restraint use is initiated and during their use. Judicious use of sitters has been shown to reduce falls and the use of restraints[28]. When danger to self or others from patient behaviors and restraints are deemed necessary, a tiered approach has been recommended by Antonelli[29] beginning with markers and paper or a deck of cards for distraction and then proceeding up to hand mitts, lap belts, or chair alarms if needed. Vest or limb restraints are the default only when other methods have been ineffective[29].

Literature from the mental health field provides some guidance to those attempting to use the least intrusive interventions for older patient behaviors that endanger themselves or others. A combination of system-wide intervention, plus targeted training in crisis management to reduce the use of restraints has been demonstrated to be effective in multiple studies[30]. In a recent randomized controlled study, one explanation the author gives

for the ineffectiveness the educational intervention is that the intervention was "at the ward level unlike other restraint reduction programs involving entire organizations."[10]. Research and clinical care in restraint reduction will likely need to be both patient-centered and systems-based in the future.

Case study revisited

Our 79 year old female with frontotemporal dementia and spinal stenosis noted in the above case pulls out her urinary catheter. The physician is called and determines that the patient's urine has been clear prior to the episode, that she has no fever, nor does she have evidence of acute illness. The patient is likely pulling the catheter out simply because of the discomfort caused by the catheter itself since the patients behavior is at the same baseline as before the catheter was inserted as determined by discussion with the staff. The patient is unable to inhibit her behavior because of the frontotemporal dementia. The physician places a call to the medical power of attorney and explains the risks of bladder infection, bladder discomfort, renal insufficiency, and overflow incontinence from untreated neurogenic bladder. This is weighed against the risk of frequent infections and bladder discomfort from a chronic indwelling urinary catheter, or damage to the urethra from pulling the catheter out. The option of periodic straight catheterization is dismissed by the medical power of attorney as being too traumatic for this demented patient who becomes agitated during this procedure.

The medical power of attorney considers the options and agrees to observation by the staff without the catheter overnight with a team conference the next day. At the conference, it was noted that overnight the patient had several episodes of overflow incontinence in spite being toileted every few hours while awake. The patient had no signs of discomfort and was changed when found to be wet. A bladder scan done at the facility showed a few hundred cubic centimeters of residual urine after the patient was noted wet and changed. The team conference yielded the informed decision to continue checking the patient frequently and changing when wet as well as frequent toileting opportunities.

The patient continued at baseline for twelve weeks until she developed urinary sepsis and the patient's medical power of attorney was contacted about additional care decisions.

Conclusion

A restraint is any device or medication used to restrict a patient's movement. Complications of restraints can be serious including death resulting from both medications and devices. Use of restraints should be reserved for documented indications, should be time limited, and there should be frequent re-evaluation of their indications, effectiveness, and side effects in each patient. Analysis of environmental and patient specific root causes of potentially self-injurious behavior can lead to reduction in the use of restraints. Education of the patients, families, and the health care team can increase the use of less restrictive alternatives.

COMPETING INTERESTS
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Review Article

What if the 'sexual headache' is not a joke?

Margaret J Redelman

Abstract
Headaches and sexual activity are often treated with humour as a typical way for women to reject male advances. However, headaches associated with sexual activity can be anything but a joke.
HSA (headaches associated with sexual activity) are by definition benign conditions but the symptoms can be the same as in serious life threatening cerebral conditions and these need to be quickly excluded at the first presentation. Most sexual headaches are of a benign nature. However, the first time an HSA occurs it can be a traumatic, frightening occurrence for the patient. HSA are capricious in nature with poorly understood pathophysiology and uncertain course of the condition. Patients need to have the situation clearly explained to them so that management can be optimal.
However, good overall management of a patient with HSA should also include discussions about possible negative sexual consequences of the HSA experience. Sexuality can be affected by HSA both during the active condition and subsequently. Sexuality must be addressed by the treating physician if the patient/couple are not to be left with an ongoing negative effect on their future sex life as a consequence of the HSA.

Keywords
sexual headache, sex, sexuality, headache

Headaches associated with or occurring around sexual activity have been recognized since the time of Hippocrates [1, 2]. Wolff [3] discussed headache during sexual activity in 1963. However, these headaches started to be formally reported in the 1970s, first by Kitz in 1970 [4] and then Paulson [5] and Martin [6] in 1974. The first published study was by Lance in 1976 [7].

Classification

This type of headache has been given many different names: benign sex headache (BSH), benign coital headache, coital cephalgia, orgasmic cephalgia, primary headache associated with sexual activity (PHSA), coital 'thunderclap' headache, primary thunderclap headache (PTH), orgasmic headache (OH) and preorgasmic headache.

In 2004the International Headache Society [8] classified HSA as a distinct form of primary headache.These benign HSA are bilateral headaches, precipitated by sexual excitement (masturbation or coitus) occurring in the absence of any intracranial disorder and which can be prevented or eased by ceasing activity before orgasm. Type 1 consists of a bilateral, usually occipital, pressure-like headache that gradually increases with mounting sexual excitement. Type 2 headaches have an explosive, throbbing quality and appear just before or at the moment of orgasm. These often start occipitally but may generalize rapidly [9].

However, there are individuals who experience patterns of HSA that do not fall within the classifications and are included as a subgroup of HSA with unusual psychopathology [10]. For example, Paulson and Klawans [5] described a rare type postural sexual headache after coitus, which is present on standing, eased by lying, accompanied by a low CSF pressure, and persists for several weeks.

International Headache Society diagnostic criteria - ICHD-2[7] classification for HSA

4.4 Primary headache associated with sexual activity
4.4.1 Pre-orgasmic headache
A. Dull ache in the head and neck associated with awareness of neck and/or jaw muscle contraction and fulfilling criterion B.
B. Occurs during sexual activity and increases with sexual excitement
C. Not attributed to another disorder
4.4.2 Orgasmic headache
A. Sudden severe ("explosive") headache fulfilling criteria B
B. Occurs at orgasm
C. Not attributed to another disorder
7 Secondary headache disorder
7.2.3 Headache attributed to spontaneous (or idiopathic) low CSF pressure

Prevalence

HSA are not common but it is generally felt that they are under-reported due to patient embarrassment [1] at telling health professionals when their headaches occur. Prevalence in the general population is reported at around 1% [11, 12] and is greater in men than in women, by 3-4 times [11, 13-16]. There appear to be two peak times of onset: in the early 20s and then around age 40 [17]. About 22% of HSA are Type 1 and 78% are Type 2 [18]. The male:female ratio is the same for Type 1 and Type 2 headache.

Pathophysiology

HSA are not clearly understood but by definition lack serious underlying disease. They are however, unpleasant, frightening, repetitive and episodic. The clinical characteristics of Type 1 suggest a relationship with tension/muscular contraction headaches [2, 13, 15, 16]. There is a significant association between the risk of having more than one cluster of HSA and the presence of tension headaches or migraine [11, 14-17, 19-21]. Biehl [11] concluded that the association between migraine and HSA is bilateral. The prevalence of migraine in HSA patients is 25-47% [15, 16, 20]. Ostergaard [14]showed that the presence of concomitant migraine or tension headache was significantly associated with the recurrence of periods lasting weeks to months in which HSA occurred. Patients without another primary headache often have only one HSA period or episode and a more favourable prognosis . Migraine is co-morbid in 30% of Type 2 as opposed to 9% with Type 1. Co-morbidity is also seen in exertional headaches, 35% of Type 2 and 9% Type 1[17, 18]. There can be simultaneous onset of benign exertional headache (BEH) and HSA [22] as well as HSA after a history of BEH [16, 22].

Several drugs have been linked in case reports to sexual headaches associated with neurologic symptoms: Amiodarone[23], birth control pills [24], pseudoephedrine [7] and cannabis [25].An interesting more recent addition to HSA is that resulting from the use of PDE5 medication to assist in erectile difficulties [26, 27].

In type 2 headaches, increased intracranial pressure secondary to a Valsalva maneuver during orgasm has been proposed as a possible mechanism. Blood pressure may increase by 40-100mmHg systolic and 20-50mmHg diastolic during orgasm [7, 28-30]. A possible disruption of autoregulation of the cerebral vasculature has also been proposed [31-33].

Classic presentation

A male patient, middle-aged, in poor physical shape, mildly to moderately overweight, and mildly to moderately hypertensive [34]. In women muscle contraction and psychological factors are often involved [34].

The typical story is that the headache occurs during sexual activity, is bilateral and stops or is less severe if sexual activity stops prior to orgasm. The duration varies from 5 minutes to 2 hours if sexual activity stops and from 3 minutes to 4 hours, with the possibility of milder symptoms up to 48hours, if activity continues.

Differential diagnosis

With the first episode it is absolutely mandatory to exclude potentially life threatening and disabling causes. A thorough history and neurological examination with the option of imaging studies and CSF examination must be conducted.

Type 2 explosive "thunderclap" headaches can be secondary to subarachnoid haemorrhage, aneurysms without obvious rupture, intracerebral haemorrhage, pituitary apoplexy, venous sinus thrombosis, cervical artery dissection, subdural haematoma, haemorrhage into an intracranial neoplasm [35], cerebral tumour [36], intracranial hypotension and hypertension, significant cervical spine disease, and ischaemic stroke [37-43] and these serious conditions need to be excluded before an HSA diagnosis can be given. HSA may present similarly to paroxysmal headaches caused by phaeochromocytoma [44].

Sexual intercourse is reported as a precipitating cause of subarachnoid haemorrhage in 3.8% to 12% of patients with bleeding from a ruptured aneurysm [35].

Course of the disease

The unpredictable clinical course falls into 2 temporal patterns: an episodic course with remitting bouts, and a chronic course [20]. In most cases the headaches occur in bouts that recur over periods of weeks to months before resolving[16, 45].

The episodic type is defined as a bout of at least 2 attacks occurring in ≥ 50% of sexual activity followed by no attack for ≥ 4 weeks despite continuing sexual activity. The chronic course is defined as ongoing HSA attacks for ≥ 12 months without remission of ≥ 4 weeks [20].

Further uncertainty is experienced by the patient as HSA does not necessarily occur in every sexual encounter [7, 19]. A characteristic of HSA is the sporadic vulnerability of patients to the headache. Episodes can occur singly, in clusters or at irregular intervals. Recurrence can occur years later.

The acute HSA attacks are usually short lasting but the overall duration of pain can vary widely [17]. The mean duration of severe pain in HSA is similar (30 minutes) in type 1 and type 2 but the mean duration of milder pain is more prolonged with type 2 (4 hours vs 1 hour). About 15% of patients suffer from severe pain for >4hours needing acute treatment. Severe pain continuing for 2-24 hours occurs in up to 25% of patients with HSA [17]. Patients with episodic HSA compared to chronic HSA have an earlier age at onset and tend to suffer more often from concomitant BEH [20].

About 30% of patients report headaches with masturbation as well as intercourse. There are also reports of HSA occurring exclusively during masturbation [46, 47] and a case of this occurring with nocturnal emission [21].

Overall HSA occurs more commonly when the patient is tired, under stress or attempting intercourse for the second or third time in close succession [48]. HSA appears in bouts lasting weeks to months and can disappear without specific treatment [14, 16]. The number of attacks within one bout ranges from 2 to 50 [17]. About 25% of patients suffer attacks without longer remissions.

Prognosis

Prognosis is usually good for HSA as it is a benign self- limiting disorder and disappears without any specific treatment in the majority of patients [17]. It is usually better if there has been only one attack, especially if it was not associated with any other type of headache.

Frese [20] concluded that episodic HSA occurs in approximately 75% and chronic HSA in approximately 25% of patients. However even in chronic HSA, the prognosis is favourable, with remission rates of 69% in patients followed over 3 years.

Management

A thorough history and examination is mandatory in a first attack.

Referral is warranted if:
Atypical story and suspicious examination
First episode of severe headache where headache still present
A recurrent episode of severe headache with longer than average duration
Neck stiffness, photophobia or vomiting
Altered consciousness or confusion
Focal neurological signs
Previous history of AV malformation, neoplasms or neurosurgery

Investigations
Computed tomography
MRI
Lumbar puncture
Cerebral angiography
Urinary catecholamine

Medical treatment

Turner [49] has provided a good review.

Pre-emptive treatment

Propanolol hydrochloride (Inderal) is effective in the prophylaxis of HSA[19]. Naratriptan 2.5mg has been reported as useful prior to sexual activity [50] but due to lower absorption rates needs to be taken more than 60 minutes before sexual activity [30]. Indomethacin 25-100mg can be taken 30-60 minutes prior to sexual activity [15, 16, 45, 51] and for acute severe pain management [20] but can cause serious gastrointestinal side-effects and is not tolerated by about 10% of headache patients [52].

Acute treatment

Triptans shorten the attack in about 50% of patients[30]. There is an 80% response rate [30]. Analgesics (ibuprofen, diclofenac, paracetamol, acetylsalicylic acid) given after onset of headache are of limited or no value in nearly all patients[45].

Other triptans, ergots and benzodiazepines have also been reported to have efficacy [5, 24, 53, 54] for acute and pre-emptive treatment for those patients not tolerating indomethacin. Taken 30 minutes before sexual activity they shorten orgasmic headache attacks in 66% of users [30].

Long term prophylaxis for longer lasting bouts or continued attacks

Options include indomethacin 25mg three times a day, propanolol 120-240mg per day, metoprolol 100-200 mg per day and diltiazem 180 mg per day [15, 19, 20, 22, 24, 45]. There is about an 80% response rate [30].

Sexual management

Trauma due to pain associated with sexual activity has the potential to affect immediate and long term satisfaction with sexual activity unless specifically addressed. HSA can be very distressing for both patient and partner with the development of fears around sexual activity and orgasm. Patients may develop patterns of impaired sexual arousal. If these fears are not exposed and dealt with, sexual problems may occur. Secondary avoidance behaviours may become established in the relationship leading to a decrease in couple's physical affection, eroticism and sexual activity. Patients must be given the opportunity to talk about sexual fears in an ongoing way, especially if HSA is chronic.

The social and relationship history will disclose areas of stress which should be evaluated and managed as best possible. In type 1 HSA where neck and jaw tension may be a factor, conscious relaxation of these muscles during intercourse may help [7]. Relaxation exercises especially concentrating on neck and shoulder tension can be done regularly and particularly before anticipating sexual activity.

Individuals often sense early in the lovemaking process whether or not HSA will occur and encouragement not to pursue orgasm on that occasion can be helpful. Some patients can terminate the headache by stopping the sexual activity or suppressing orgasm and about 51% can lessen the intensity of pain by being more sexually passive [18].

Advice on continuing to engage with the partner despite ceasing or modifying one's own sexual arousal needs to be given. Having a disappointed or resentful partner increases the distress of the condition so partner needs have to be discussed. Patients often have difficulty talking about sexual issues with both their partner and their doctor, therefore the doctor needs to be the one to raise the subject.

A brief sexual history will outline the love-making practice and modification to sexual positions, especially where neck tension is exaggerated, may help. In one report, the advice to engage in intercourse more frequently but less strenuously resulted in a reduction in headaches [5].

Avoiding sexual activity and strenuous activities until totally symptom free has been recommended by some [13, 22, 24, 55]. This may be difficult to follow as the capricious nature of HSA makes knowing when they have stopped difficult.

Conclusion

HSA are benign, but because they can mimic serious conditions, patients need to be properly assessed before reassurance is given and management of HSA started. Because pain can alter sexual experience and behaviour around sexuality for the patient and the couple, this aspect of patient wellbeing must be addressed by the treating physician for good holistic management. As not everyone is comfortable with addressing sexuality with patients, respectful acknowledgement of the situation and appropriate referral can be a useful approach

COMPETING INTERESTS
None declared
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Viewpoint

Psychiatry in descent

Francis J Dunne

'The following article is another in a series of critical essays examining the current status of Psychiatry in the NHS'

In therapy

"*Good advice is often a doubtful remedy but generally not dangerous since it has so little effect.' Carl Jung (1875-1961)*

The word 'therapy', as defined by the Oxford Dictionary as 'to treat medically', is derived from the Greek *therapeuein,* meaning to minister. Nowadays it can denote any treatment from massage therapy to music therapy. In mental health it has become synonymous with counselling or psychotherapy. Drug therapy, believe it or not, is included in the definition, though is frowned upon by many in the mental health industry, and is often the subject of derisory and ill-informed comments from both medical and non-medical practitioners. Many medical doctors who decide to embark on a career in psychotherapy generally forfeit all their knowledge of physiology, biochemistry, anatomy, pharmacology and many other subjects, in the pursuit of an ideal that somehow all life's problems can be resolved through a particular brand of talking therapy. One wonders why they spend many years in medical school and in postgraduate teaching. Why devote all that time studying subjects, which have no relevance to common or garden psychotherapy? Would it not be more practical for those who specifically want to pursue such a career in psychotherapy to enrol in a psychotherapy training college, and then 'specialise' in whatever form of psychotherapy they aspire to? Such individuals, instead of wasting years training as medical doctors, could receive a diploma or certificate to practise psychotherapy. Likewise, you do not need to be a neurosurgeon to become a neuroscientist, or a physician to study virology. For some reason, however, scientists, including innovators in the fields of medicine and surgery, seem to be disparaged by both medical and non-medical psychotherapists, and seen as persons who can only conceptualise individuals as molecules, or objects to be examined with sophisticated machinery. Psychotherapy seems to induce a state of delusional intellectualism among some of its members, it would seem. Such intellectualism, if it be described as such, portrays an affected and misguided arrogance towards matters scientific. Yet curiously, published papers in mental health journals or in the press, when written by 'experts' are often interspersed with the words 'science' or 'scientific' even when they are little more than observations, studies, or comparisons between populations receiving a particular mode of this therapy or that therapy. We are not talking about advances in the treatment of neuroblastoma or other cancers here or a cure for dementia. It is one thing to describe Addison's disease; it is another to discover the cause.

The panacea

'Nice people are those who have nasty minds.' Bertrand Russell (1872-1970)

The necessity for 'therapy' now seems to be deeply ingrained in our culture and the army of pop psychologists and psychiatrists, non-biological therapists, and agony aunts increases, it seems, by the day. In the media what is quoted as 'research' and passed off as science, is often no more than a street survey, or opinion poll on a current fad or passing headline grabber, rather like those 'we asked a hundred people' questions posed on popular family quiz shows. The therapy bandwagon rolls on and is quite lucrative if you are fortunate enough to capture the market with your own brand of snake oil cure to life's woes. Admission is free to the Mind Industry and furthermore, there are no compulsory, nationally agreed standards for the conduct and competence of non-medical psychotherapists and counsellors. Even if removed from the membership of their professional body for inappropriate conduct say, therapists can continue to practise, there being no legal means to prevent them from doing so. Most members of the public are unaware of this lack of statutory regulation. It is not surprising then that many 'therapists' flagrantly sell their product and any attempt to question the authenticity of a particular 'cure' is met with vitriol and feigned disbelief. After all, one has to guard one's source of income. The author Richard Dawkins was subject to such venom and hostility when he dared to question the reasons and need for religion in his book *The God Delusion*. Woe betide any practitioner who dares to criticise the favourable results of 'carefully conducted positive outcome studies' on, say, cognitive therapy, even when one's own clinical experience attests to the opposite. Of course, some therapies work, some of the time, but not because of the outlandish claims made for them; rather, they work best when a 'client' harnesses the energy and motivation to get better and 'chooses' one brand of therapy over

another, or feels at ease with a therapist who is empathic and understanding, much as one might confide in a best friend, rather than any inherent benefit from the 'therapy' itself. Certain therapies work because they have an intrinsic behavioural component to them, for example, dialectic therapy for 'borderline personality' disorder (as real a condition as 'sociopathic' disorder), or cognitive behaviour therapy for obsessive-compulsive disorder and phobic disorders. With other therapies one would almost have to admit feeling better given the enormous sums of money involved say, for a one-week course in a therapeutic healing centre. After all, it would be painful to admit an expensive holiday being a waste of time when a lot of hard-earned money has been spent.

The enemy within

'Sorrow and silence are strong, and patient endurance is godlike.' Henry W Longfellow (1807-1882)

Why does one who is vehemently opposed to psychiatry want to become a psychiatrist? Do as many medically qualified psychotherapists as non-medical therapists dismiss the role of biology in the causation of mental health disorders? Why do we speak of anti-psychiatrists and not anti-cardiologists? What about the claims for psychotherapy itself? Is it possible truthfully to scientifically evaluate whether or not it works? Criticism comes from within its own camp. To paraphrase one well-known psychologist, 'Psychotherapy may be *good* for people, but I wish to question how far it *changes* them, and I strongly cast doubt on any assumption that it *cures* them'.[1] The irony now is that the therapies themselves are being 'dumbed down', sometimes aimed at a younger audience to court popular appeal. Trite and stultifying sound bites such as 'getting in touch with your feelings', 'it's good to cry', 'promote your self-esteem', 'search for your inner child', and many other inane phrases flourish. Failure to display distress or intense emotional turmoil outwardly (say, after a bereavement), is seen as weak, maladaptive, and abnormal, instead of being viewed as a strength, a mark of dignity, and an important way of coping. The corollary of course, is the spectacle of some psychiatrists, because of their medical training, endeavouring to explain every aspect of mental health psychopathology in terms of neurotransmitters and synapses. And then there is the scenario of non-medical 'scientists' critically evaluating and expounding on subjects completely outside their remit, for example, uttering pronouncements say, on the neuropharmacology of depression, or the reputed reduction in hippocampal volume caused by posttraumatic stress disorder, when they are not qualified to do so, having only a superficial knowledge of pharmacology and/or neuroimaging respectively. Instead of asking the engineer's advice on the safety strength of a steel column supporting a bridge, why not ask the carpenter! The absurdity knows no bounds.

It seems that all life's problems are self-inflicted or caused by 'society' or faulty upbringing. Back to the schizophrenogenic mother then. It is up to the client to seek the therapist's help and advice by way of talking cures to set him/her on the road to recovery. To be fair to non-medical therapists and lay counsellors, some psychiatrists do not believe in the genetics of, or neurobiological contribution to, mental health. Some even believe mental illness to be a myth! Imagine an electrician who does not believe in electricity, or to compare like with like, an oncologist who does not believe in cancer. Many decades ago the psychiatrist Thomas Szasz described psychology as *pseudoscience* and psychiatry as *pseudomedicine*[2] .Since then others have reinforced Szasz's conclusions. Who can blame them? To illustrate by one example, many court cases (particularly in the forensic field) involve a psychiatrist/psychologist giving 'expert' testimony for the defence with the prosecution in turn calling for a psychiatrist/psychologist to offer a contradictory opinion on say, the defendant's fitness to plead. The prosecution says the defendant is acting, the defence argues the defendant is suffering from a mental disorder. No surprises there as to why psychiatry has descended into farce.

Psychotherapy is all talk

'There is no art to find the mind's construction in the face.' William Shakespeare (1564-1616)

One outspoken critic has had the courage, some might say the audacity, to assert that the psychology/psychiatry therapy hoax is still as widespread and dangerous as it was when the neurologist Sigmund Freud first invented what she describes as 'the moneymaking scam of psychoanalysis.'[3]. Briefly, at the core of psychoanalysis lies the principle that the id, ego and superego (not originally Freud's terms) are considered to be the forces underlying the roots of psychological turmoil. The id, or pleasure principle, is in conflict with the superego or conscience (the conscious part of the superego) and the resultant outcome is mediated by the ego. Any interference with this delicate balance results in symptoms. However, this simplistic theory has come in for much criticism over the years and many scholars now consider the claims of psychoanalysis as having little credibility. It is not philosophy and it is certainly not science. Research in this area is fraught with even more methodological problems than say, with cognitive therapy studies. There is no way of testing analysts' reports or interpretations reliably, and their conclusions are speculative and subjective. One eminent psychotherapist pronounced 'as far as psychoanalysis is concerned, the logistical problems of mounting a full-scale outcome study are probably insurmountable.'[4] It is impossible to develop a truly valid research protocol in either cognitive or psychoanalytic treatments to account for all the subtle, different variables that make individuals so unique. How can one research the mind? There are no specific blood tests and brain investigations that diagnose mental illness in the same way one might

diagnose neuroleptic malignant syndrome or Parkinson's disease respectively, at least not yet. Measuring scales are a very crude way of conducting research into mental health, and are not always objective, particularly when researchers are keen to have a favourable result. This applies also to drug trials, I hasten to add.

Many people feel better simply by seeing and discussing their troubles with a friend, their physician, a member of the clergy, or their next-door neighbour for that matter. Such individuals are usually more than prepared to give considerable time to listening sympathetically and offering possible solutions to often intricate and personal problems. Nonetheless, talking about a negative experience or trauma does not necessarily alleviate the distress or pain felt by that event. One wonders then why a 'client' would be expected to get better simply by insisting changing his/her 'negative set', for instance, by doing homework exercises for the teacher/therapist. No doubt countless individuals move in and out of therapy and support groups; some may even benefit from self-help books. However, it is the earnest fatuity in such books that is so tragically funny, and that people take them so seriously is even more worrying.[5] Some 'clients' find therapy a waste of time, but since they do not return for their follow-up sessions it is assumed they are well, or have moved on, or are simply unsuitable. On the other hand, there are countless individuals who find an inner resilience to withstand and improve themselves through their own volition, with a few prompts on the way, rather like finding one's way through unfamiliar territory with the aid of a street map. Likewise, drug treatment is of very little value if one's relationships are in disarray, or an individual is in great debt, for instance. The 'worried well' simply require practical help from appropriate advisors, not health care professionals and should they wish to spend money on counsellors and therapists, that is for them to decide.

Common sense and nonsense

'He who exercises his reason and cultivates it seems to be both in the best state of mind and dear to the gods.' Aristotle (384 -322 BC)

We have now reached a point where minor setbacks and irritations are seen as obstacles to be treated. By adopting this attitude we are succumbing to the might of the Therapies and Mind Industry, eliminating those experiences that define what it is to be human. Individuals freed from moral duty are now patients or victims. This abnegation, abdication and suffocation of individual responsibility for the sake of self-esteem is creating a society which needs only to be placated and made content.[3] Anything that causes dismay or alarm is a trauma, and therefore needs therapy. Any crime or misdemeanour is not our fault. We have a psychological condition that absolves us from every sin or ailment. The opposite scenario is whether through scientific ignorance or a refusal to acknowledge that the human genome may play a part, perhaps both, some therapists accuse organic theorists of being 'too ready' to favour biological models, believing that dysfunctions in neuronal circuits have no part to play in 'disorders of the psyche'. We are not all at the mercy of our neurotransmitters, they cry. Neither view is accurate. Psychoanalytic psychotherapy is no exception either. The nub of psychoanalysis is the therapist's analysis of transference and resistance, which distinguishes this form of psychotherapy from all other types. With this brand of therapy absurd interpretations abound, leading one psychotherapist to openly admit that 'jargon is often used to lend a spurious air of profundity to utterances which are nothing of the kind'.[6] The author Frederick Crews writes: 'I pause to wonder at the curious eagerness of some people to glorify Freud as the discoverer of vague general truths about human deviousness. It is hard to dispute any of these statements about "humans", but it is also hard to see why they couldn't be credited as easily to Shakespeare, Dostoevsky, or Nietzsche - if not indeed to Jesus or Saint Paul - as to Freud'.[7]

One particular concept that is difficult to sustain is that repressed memories of traumatic events lead to psychiatric disorders. That such repressed memories in some instances encompass sexual preferences towards one or other parent, is even more perplexing to most people. The Oedipus and Electra complexes, expounded by Freud and Jung respectively, were founded on Greek mythology, hardly the basis for scientific study. Psychoanalysis set out to cure a disorder by uncovering repressed memories. However, traumatic memories by their very nature are actually difficult to 'repress'. Of course individuals do forget. This is a normal part of the human condition. Memories are recollected or resurrected by association of ideas; multiple-choice format questionnaires work on the same principle. Familiar sights, smells and sounds, as famously depicted in Marcel Proust's *A La Recherché de Temps Perdu* ('and suddenly the memory revealed itself. The taste was that of the little piece of madeleine cake') often conjure up previously 'forgotten' memories, what used to be described as involuntary memory. Forgetting does not always equate with psychopathology; forgetfulness is common and becomes more common with age. In psychiatric treatment electroconvulsive therapy (ECT) is associated with a high prevalence of memory disturbances, often irreparable. With organic disorders, memory channels or traces are damaged, for example, through alcohol, or subcortical injury.[8]However, even in Alzheimer's disease, at least in the early stages, memories are often not totally erased, a fact utilised in *reminiscence therapy*. Memories in healthy people are not suppressed or repressed. Not wanting to talk about some painful issue is not necessarily 'denial', nor does it denote a fear of unleashing repressed/suppressed memories.

After the Trauma

'*We seldom confide in those who are better than ourselves.' Albert Camus(1913-1960)*

Mental health care workers often speak of posttraumatic stress disorder where memories of an especially overwhelming and

upsetting event are ever-present and particularly distressing, leading to panic feelings, flashbacks, and recurrent nightmares. Such memories may be easily evoked, sometimes merely by watching a documentary, reading a news item, listening to a radio programme, and so forth. In other words, patients are all too quickly reminded of them - the memories are very vivid, not repressed. Often people simply do not want to be reminded. They are not in denial – they are simply avoiding the issue and should be allowed to do so. Whereas formerly such traumas were associated with catastrophic events such as the Holocaust or major natural disasters, nowadays the term posttraumatic has become over-inclusive. Some people have 'trauma' imposed on them in the form of invidious suggestions that they were subject to abuse of one form of another. On the contrary, there is no evidence that any of Freud's patients who came to him without memories of abuse had ever suffered from sexual abuse. Furthermore, Freud ensured that his theory of repression could not be easily tested, and in practice the theory became 'unfalsifiable'.[9] Traumatic memories of abuse are very difficult to forget, and patients struggle to suppress them, in the author's experience.

Undoubtedly, some memories are painful, and generally speaking, there are individuals who *want* to 'forget the past' in order to 'move on', which would strike most of us as being a reasonably healthy approach in certain circumstances. Many patients, for instance, would want to 'move on' to a healthier, more satisfying relationship, change job, alter their lifestyles, and so forth. When it comes to major catastrophic events, memories are not preconscious or unconscious: they are very often disturbingly real, and very difficult to live with; in many cases time is the only 'healer'. Some traumatic memories never fade and in many cases no amount of talking will erase the painful memories. Witness the Holocaust survivors and those subject to horrendous atrocities throughout the Pol Pot regime, for example.

It is difficult to ascertain therefore whether so-called defence mechanisms such as repression or denial are truly separate entities operating in the human psyche, or merely part of a conscious natural survival instinct to ward off painful stimuli. How can such mechanisms be unconscious when it is commonplace to hear of people ironically talking about 'being in denial'? Individuals who attempt to overcome their own addictions for example, are seen as suffering from a 'perfectionist complex', and reluctant to admit their failings. In other words, acknowledge you are unable to cope and are in denial about the true nature of your affliction and you will then be offered a place in the recovery programme.[5]Therapists see denial as a mechanism deployed to avoid the pain of acknowledging a problem and taking action to seek help. It is not medical bodies but grass roots campaigners who are foremost in demanding that every 'traumatic' or 'problematic' condition be medicalised, creating more opportunities for counselling intervention.[10] Hence the new breed of disorders to include shyness, inattentiveness, road rage, trolley rage, sex addiction, shopping addiction, internet addiction and so forth.

Beyond therapy

'We are all born mad. Some remain so.' Samuel Beckett (1906-1989)

Talking therapy is now the new religious cult and is what people have now turned to in order to find solace or answers ('discover your real self'), and even cope with often inconsequential day-to-day events. The constant, pervasive emphasis on counselling diminishes the capacity of healthy people to confront commonplace problems they encounter in ordinary day life. Normal variants in behaviour are considered pathological and 'psychologised' or 'medicalised'. Psychobabble prevails. We all need therapy or a pill. More and more 'disorders' are being invented. The endless proliferation and demand for 'expertise' in all areas of life is eroding the willingness of those who are best positioned to offer at least measured advice, accumulated from years of experience. There are no 'experts in living' and some individuals need to steer away from their excessive dependency and seeking self-approval of others who claim to be. Kierkegaard once wrote of people 'taking refuge in a depersonalized realm of ideas and doctrines rather than confronting the fact that everyone is accountable to himself for his life, character and outlook'.[11] In the words of John Stuart Mill, 'Ask yourself whether you are happy, and you cease to be so.'

Competing Interests
None Declared
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E-Interview

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Interview with Professor Elisabeth Paice

Professor Elisabeth Paice is currently on secondment to NHS London having been appointed to the new post of Acting Director of Medical and Dental Education from her role as Dean Director at London Deanery. The new role will ensure that the right number of doctors and dentists have the right training to deliver the service ambitions outlined in Healthcare for London. Elisabeth will be leading on the Medical and Dental Education Commissioning System (MDECS). This is the name of the programme of work that will manage the changes to postgraduate medical and dental training.

She was born in Washington DC, brought up in Canada, and studied medicine first at Trinity College Dublin and later at Westminster Medical School. She was the originator of the 'Hospital at Night' concept; developed the 'Point of View Surveys'; chaired PMETB working parties on Generic Standards and the National Trainee Survey and has published variously including on doctors in difficulty; workplace bullying; women in medicine. She was Chair of COPMeD, Conference of Postgraduate Medical Deans, from July 2006 to July 2008.

How long have you been working in your speciality?

I have been a full-time postgraduate dean since 1995. Before that I was a consultant rheumatologist for 13 years.

Which aspect of your work do you find most satisfying?

I get great satisfaction out of developing and implementing new ideas, especially when they work well enough to be taken up by others. I think most doctors have a creative streak and sometimes bureaucracy can damp this down. One of the reasons why medical education and training is so enjoyable is that it has to keep changing because of changes in the way the service is developing. There are standards to be met, of course, and regulators to satisfy, but within those constraints there is plenty of room for innovation. The better the quality of education and training, the better and safer the care of patients.

What achievements are you most proud of in your medical career?

As Dean Director of London, I have been very proud to lead postgraduate medical and dental education in one of the world's great cities, with its five world-renowned medical schools, numerous centres of clinical excellence, and over 10,000 trainees. In order to understand trainees' views, I introduced a regular survey through which they could voice their views about the quality of training they were receiving. I was very pleased when this formed the basis of the very successful National Trainee Doctor Survey, now embarking on its fourth iteration. This survey has enabled postgraduate deans across the UK to identify departments where training is not meeting the minimum standards for training and to take appropriate action.

Other achievements of which I am proud include the development of a multiprofessional team-based approach to out of hours services, known as the Hospital at Night initiative, which has improved patient safety while providing a solution for reducing the hours of junior doctors. Most recently I am delighted with the success of London's Simulation and Technology-enhanced Learning Initiative (STeLI) which recently won the prestigious Health Service Journal Award for Patient Safety.

Which part of your job do you enjoy the least?

I least enjoy dealing with performance issues, whether internal to my staff or among trainees or their trainers.

What are your views about the current status of medical training in your country and what do you think needs to change?

Medical education is recognized in the UK as being a vital factor in providing the high quality doctors necessary for a high quality health service. It needs to be better resourced, and in particular every doctor with responsibility for educational supervision needs to have the training, the time, and the tools

to do a good job. The way in which training has traditionally taken place, known as the 'apprenticeship model', is no longer suitable because of restrictions on the hours of work. I am all in favour of these restrictions, because long hours have a negative impact on learning and pose a risk to the health and safety of both doctors and patients. But we need radical change in the way we depend on doctors in training to provide out of hours cover and we need to find robust ways to ensure they gain the practical experience they need.

How would you encourage more medical students into entering your speciality?

I would strongly encourage any medical student to consider taking an interest in medical education from the start. Whatever the field of medicine that they enter, there will inevitably be an expectation that they will teach the next generation of doctors and of other healthcare professionals. Teaching is increasingly being recognized as one of the duties of a doctor, and like anything else, the more effort you put in, the more rewarding the outcomes.

What qualities do you think a good trainee should possess?

Trainees need to have a solid grounding in the basic sciences, because it is the foundation on which their postgraduate training will build. They need to be both conscientious and curious, doing what is required of them, but also going the extra mile in the search for knowledge. They should be motivated by the desire to make a positive difference to the lives of others, because I believe that is the only motivation that stands the test of time.

What is the most important advice you could offer to a new trainee?

Read the curriculum, establish what is expected of you and what you can expect from your seniors and your team, and engage with the educational programme.

What qualities do you think a good trainer should possess?

Kindness, honesty, expertise - and a passion for developing these qualities in their juniors.

Do you think doctors are over-regulated compared with other professions?

No, it is a profession in which we can potentially harm others, regulation is a necessity.

Is there any aspect of current health policies in your country that are de-professionalising doctors? If yes what should be done to counter this trend?

The responsibility for the professionalism of a doctor lies with the doctor. There are no policies in the UK that de-professionalise doctors.

Which scientific paper/publication has influenced you the most?

I have been heavily influenced by the body of work by Charles Czeisler in the USA and Philippa Gander in New Zealand about the impact of long hours and sleep deprivation on health, safety, errors and retention of learning of doctors in training.

What single area of medical research in your speciality should be given priority?

Simulation technology.

What is the most challenging area in your speciality that needs further development?

Fitting adequate training into a 48 hour week without lengthening the duration of training

Which changes would substantially improve the quality of healthcare in your country?

Improving the training of general practitioners

Do you think doctors can make a valuable contribution to healthcare management? If so how?

All doctors need to learn to look after the system of care as well as the patient in front of them. Medical leadership is crucial to modernizing services. During training all doctors should be involved in quality improvement initiatives and all should learn how to champion change effectively.

How has the political environment affected your work?

The most recent impact has come from the national policy to introduce a separation between the commissioning of education and its provision. This has meant a reorganization of the way we work, with much of the work we did being commissioned from lead providers. While change is always disconcerting, there are real benefits to be realized from this one, in particular a better alignment between service and education planning.

What are your interests outside of work?

Looking after our four delightful grandchildren

If you were not a doctor, what would you do?

When I was at school I planned to write plays, but a medical career has sated my appetite for drama.

Miscellaneous

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Sit, Listen, Learn !

Shamim Sadiq

(A Poem written by a doctor about ADHD)

Competing Interests
None declared
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He'd try to sit, couldn't hold on for long,
Fidgety, restless, frustration would only prolong
Tried hard to listen to parents and teacher,
Distracted, voices sounding like a background clutter
Kept working on sitting listening and learning
Realized wasn't at par with kids and his sibling
This sentence would redundantly echo in his head
"Sit, listen, learn" you dumb head!!!

"How come life can't be better than what I feel?"
Why is it so hard for me to deal
My head hurts after constant listening,
Nothing I do is gratifying
They say, am not in same learning standard curve as other kids
My parents are worried for me, not understanding my needs
Have tried all avenues, anger, love , comfort, compassion,
Yet everyday is a challenge for them to find a solution

They interpreted his "not sitting still as restlessness",
Not listening and disruptive behaviour as impulsiveness
His attention level considered as poor learning skills
parents embarrassed, trying to overcome his hills

"Trust me", He'd say, "you don't understand, I'm trying my best"
Parents instead kept echoing sit, listen and learn, and accept it as a test
All this felt repetitive and redundant in his head,
Until someone said "maybe something is wrong with his brain instead"
Suggested see a doctor who might help clear the clutter away
Who observed his behaviour without decision to change him right away,

That's when he told the parents "Your child has had attention deficit disorder"
They felt was a mental taboo, and asked not to speak about it louder
The doctor insisted on strict compliance and periodic follow-up
Meds, mental stimulation exercises worked, felt no more like empty cup

Before he knew, he was sitting longer, nothing felt like clutter
Realized the deficit had prevented him from thinking better
Parents and doctors worked together, we salute them for the joint effort,
helped him evolve into the person altogether different

He listens to his inner and external suggestions alone and in group discussions,
Has learned realities of life, applying them in every day decisions
Sits down for hours working on his research projects
Sit, listen, learn, now all sound real, not mystical acts