A multicentre audit of single-use surgical instruments (SUSI) for tonsillectomy and adenoidectomy

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ABSTRACT

INTRODUCTION Prions are resistant to conventional sterilisation procedures and, therefore, could be transmitted iatrogenically through re-usable adenoid and tonsil surgical instruments. Using disposable instruments would avoid the risk of transmission. We present the results of a complete audit loop using BBraun single-use surgical instruments (SUSI).

PATIENTS AND METHODS This was a prospective multicentre audit. Surgeons were asked to fill in a standardised questionnaire recording details including postoperative complications, and evaluation of each piece of equipment compared with their own experience of conventional re-usable instruments. In the first cycle, constructive criticisms of the instruments were noted and the manufacturers modified the instruments accordingly. A second cycle of audit was subsequently undertaken.

RESULTS A total of 86 patients were audited in the first cycle and 97 in the second cycle. Postoperative haemorrhage rate for both cycles was well within acceptable range. In the first audit cycle, surgeons generally found the Draffin rods, Boyle-Davis gag and bipolar diathermy forceps of poor quality and difficult to use. These were redesigned and, on repeat evaluation during the second audit cycle, were found to be just as good, if not better, than the re-usable instruments.

CONCLUSIONS This study suggests that SUSI may be just as good as re-usable instruments. Furthermore, they may be more cost effective.

KEYWORDS

Disposable surgical instruments – SUSI – Tonsillectomy – Adenoidectomy – vCJD

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In 1995, the first case of variant Creutzfeldt-Jakob disease (vCJD) was documented in the UK.¹ Since then, over 150 cases have been diagnosed.² The prion protein associated with vCJD has been isolated in tonsillar tissue in those infected before the clinical manifestation of the disease. Whilst the incidence of vCJD has remained low, human prion diseases can have incubation periods of up to 40 years.² Prions are resistant to conventional sterilisation procedures and, therefore, could be transmitted iatrogenically through re-usable adenoid and tonsil surgical instruments.³ Using disposable instruments would avoid the risk of transmission.

In 2001, The Spongiform Encephalopathy Advisory Committee (SEAC) raised concerns about the theoretical possibility that tonsillectomy and adenoidectomy surgical equipment may be a potential vector of transmission of the

prion between patients.⁴ This was heavily based on the resistance of prion particles to inactivation using standard sterilisation techniques. It became apparent that the use of re-usable tonsillectomy and adenoidectomy equipment in young patients might cause a future vCJD epidemic.⁵

Frosh *et al.*⁶ calculated that, given the prevalence of pre-clinical vCJD being 1 in 10,000, an average tonsillectomy kit in England has a 6.4% chance of being contaminated over 10 years and, out of 250 centres that perform tonsillectomies, there is a 32% chance of having a contaminated instrument set in surgical theatres. The potential risk of cross-transmission via surgical equipment is 10⁵–10⁶ greater than ingesting vCJD-infected food products. In 2001, the UK Department of Health undertook a risk assessment of cross-transmission of the prion via surgical instruments and calculated (using the most pessimistic variables)

Figure 1 Examples of phase 2 SUSI instruments.

that this method of infection could account for 5–10% of all vCJD cases in the future.⁷

Standard sterilisation techniques failed to eradicate prions from instrument surfaces and nearly 50% of sterilisation units fail to meet ISO 2000 standards. In a study of 241 patients with confirmed vCJD, there was a significant proportion with a surgical history. The risk of vCJD increases progressively with consecutive procedures up to three operations. Minimisation of this risk can only occur if decontamination protocols are improved to show effective eradication of the prion or the universal practice of using single-use surgical equipment.

Prompted by the lack of *in vivo* diagnostic tests, the long asymptomatic latent period of vCJD, and an ineffective autoclaving processes, the UK Department of Health requested that all tonsil and adenoid surgical equipment be made disposable. SUSI instruments were introduced at this time along side many other disposable instruments.

Following the use of disposable instruments, there was anecdotal evidence of increased rate of secondary haemorrhage, which was substantiated by a number of regional audits and, more recently, by the National Prospective Tonsillectomy Audit.^{5,8,9,11} As a result, the use of disposable instruments was no longer compulsory in England. The main criticism was the design of the bipolar diathermy forceps, which caused dissipation of excessive electrical energy to surrounding tissue. A technical flaw of the coagulation forceps might have been responsible for this increased electricity and the resulting damage to surrounding tissue. Surgeons generally felt that the new equipment was more

difficult to use, not of a high enough standard, and would compromise patient safety.

In order to circumvent these problems, BBraun endeavoured to produce a new generation of high-quality, single-use, surgical instruments (SUSI; Fig. 1). These instruments were made of a high-grade polymer rather than steel, tested to meet ISO standards, and were the first commercially available instruments of their type. All equipment was CE marked, that is, all surgical devices complied with all the essential requirements of the Medical Device Directive. They were designed to be similar to conventional re-usable instruments, be acceptable to surgeons, have no cross-contamination risk, be ecologically friendly, and constitute good value for money.

The company subsequently invited four ENT units to carry out a prospective audit in order to evaluate the surgeons' assessment of the instruments as well as safety and postoperative complications. There were no financial incentives except that the instruments were provided free of cost. In what follows, we present the results of this multicentre prospective audit.

Patients and Methods

The four audit centres were the: (i) Royal National Throat Nose and Ear Hospital, London; (ii) John Radcliffe Hospital, Oxford; (iii) Royal Free Hospital, London; and (iv) Bromley Hospital. For each patient, consent was obtained and there were no specific inclusion or exclusion criteria. There was no operator selection for the purpose of this audit. Surgeons

were asked to fill in a standardised questionnaire after performing tonsillectomy, adenoidectomy or both. Surgeons were to indicate whether in their opinion each instrument was better, same or worse than the conventional re-usable steel equivalent to which they were accustomed. Specific comments could also be recorded. Re-usable instruments were available to the surgeon as a back up in case any SUSI equipment failed. Patients were notified of the use of the new instruments and informed consent obtained. The first audit cycle included 86 patients and took place from August 2002 to July 2003. It highlighted concerns about specific instruments, which were conveyed to the manufacturer. The problems were addressed and rectified and a second audit cycle, involving 97 patients, was undertaken between August 2003 and July 2004.

Data analysis

Data were recorded using a standardised questionnaire. On completion of the procedure, the surgeon filled in details as listed in Appendix 1.

Postoperative events

Upon discharge, each patient was given a standard postoperative management advice sheet. Any untoward postoperative events within 3 weeks of the operation were recorded on the questionnaire. Patients and parents were advised to contact the ward or their nearest accident and emergency department in the event of postoperative bleeding.

Disposal

After each operation, SUSI were incinerated at temperatures exceeding 600°C. The main waste products are H₂O and CO₂; other by-products (carbon monoxide, hydrocyanic acid, ammonia and nitrogen oxides) are generally toxic when inhaled

at high concentrations, but, in the context of this incineration, they are produced at levels comparable to burning wood.

Results

First cycle

PATIENTS AND OPERATIONS

In total, 86 patients undergoing tonsillectomy and/or adenoidectomy were audited. Data on 505 individual instruments were recorded; 191 (37.8%) were deemed worse than conventional re-usable instruments by the surgeon. The average age of the patient was 19.1 years (range, 2–93 years). When subdivided into age groups, 38 were young children (0–12 years), 10 were teenagers (13–17 years), 26 were adults (18–64 years) and 1 was a senior (over 65 years). Overall, 36 patients were male (41.9%) and 50 were female (58.9%). The operations were performed, collectively, by 25 SHOs, 33 SpRs, 2 staff grades, and 24 consultants. Two operations had no record of grade of operator (Fig. 2).

INDICATION FOR SURGERY

In the series, 55 patients had recurrent tonsillitis, 10 had obstructive sleep apnoea, 1 had a peritonsillar abscess, 4 required a tonsillar biopsy, 4 had nasal obstruction/adenoiditis, 4 had OME, and no record of indication was made for 19 patients. Table 1 records the number of times each SUSI was used and the cumulative opinion of all the surgeons who took part in the audit.

POSTOPERATIVE HAEMORRHAGE

The following figures describe the number of episodes and types of haemorrhage associated with the operation on the 86 patients: (i) returned to theatre within 24 h, 3 (3.5%); (ii)

Table 1 Surgeons' assessment of SUSI (first cycle)

SUSI equipment	Used	Worse	Same	Better	No response
Boyle-Davis gag and tongue blade	79	48 (60.8%)	28 (35.4%)	1 (1.3%)	2 (2.5%)
Draffin rods	73	29 (39.7%)	39 (53.4%)	3 (4.1%)	2 (2.8%)
Dennis-Browne forceps	78	23 (29.5%)	39 (50%)	5 (6.4%)	11 (14.1%)
Gwyn-Evans dissector	35	5 (14.3%)	16 (45.7%)	10 (28.6%)	4 (11.4%)
Pillar retractor	60	7 (11.7%)	46 (76.7%)	2 (3.3%)	5 (8.3%)
Bipolar forceps	80	60 (75%)	14 (17.4%)	3 (3.8%)	3 (3.8%)
Toothed forceps	15	3 (20%)	10 (66.7%)	0 (0%)	2 (13.3%)
Scissors	50	11 (22%)	25 (50%)	8 (16%)	6 (12%)
Knot pusher	11	0 (0%)	7 (63.6%)	4 (36.4%)	0 (0%)
Snare	12	2 (16.7%)	4 (33.3%)	6 (50%)	0 (0%)
Adenoid curette	12	3 (25%)	6 (50%)	0 (0%)	3 (25%)

secondary haemorrhage, 3 (3.5%); (iii) secondary haemorrhage requiring surgery, 0; and (iv) need for blood transfusion, 0.

GENERAL COMMENTS

After the first audit cycle, it was felt that the SUSI equipment

was serviceable, but the bipolar forceps, Boyle Davis gag and Draffin rods were significantly more difficult to use than re-usable equivalents. The manufacturer was informed of these results and, in turn, implemented design modifications based on specific criticisms.

Table 2 Surgeons' assessment of SUSI (second cycle)

SUSI equipment	Used	Worse	Same	Better	No response
Boyle-Davis gag (modified) and tongue blade	86	27 (31.4%)	56 (65.1%)	2 (2.3%)	1 (1.2%)
Draffin rods	82	17 (20.7%)	59 (72%)	0	6 (7.3%)
Dennis-Browne forceps	89	14 (15.7%)	65 (73%)	3 (3.4%)	7 (7.9%)
Gwyn-Evans dissector	35	7 (20%)	25 (71.4%)	1 (2.9%)	2 (5.7%)
Pillar retractor	85	4 (4.7%)	72 (84.7%)	1 (1.2%)	8 (9.4%)
Bipolar forceps	92	16 (17.4%)	51 (55.4%)	19 (20.7%)	6 (6.5%)
Toothed forceps	10	2 (20%)	6 (60%)	0	2 (20%)
Scissors	51	9 (17.6%)	39 (76.5%)	3 (5.9%)	0
Knot pusher	11	1 (9.1%)	5 (45.5%)	2 (18.2%)	3 (27.2%)
Snare	2	0	0	1 (50%)	1 (50%)
Adenoid curette	15	1 (6.7%)	10 (66.6%)	1 (6.7%)	3 (20%)

Second cycle

In the second cycle of the audit, the newly modified instruments were evaluated using similar assessment forms (Fig. 3; Table 2).

PATIENTS AND OPERATIONS

Ninety-seven patients were audited in the second cycle. Data on 588 individual instruments were recorded; 108 (18.4%) were deemed worse than conventional re-usable instruments by the surgeon. The average patient age was 17.5 years (range, 3–78 years). When subdivided into different age groups, 44 were small children (0–12 years), 8 were teenagers (13–17 years), 39 were adults (18–64 years) and 2 were seniors (65 years and older). Fifty-three patients were male (54.6%), 42 were female (43.3%) and 2 patients had no gender recorded (2.1%). Collectively, 26 SHOs, 49 SpRs and 17 consultants operated. Five operations had no record of grade of surgeon.

INDICATION FOR SURGERY

In this series, 63 patients had recurrent acute tonsillitis, 20 had obstructive sleep apnoea, one patient required a tonsillar biopsy and 13 patients had no record of indication.

POSTOPERATIVE HAEMORRHAGE

No haemorrhages relating to the operations occurred.

Surgical procedure and effectiveness

In all operations, SUSI achieved their functional goals – that is, the complete removal of the tonsils as well as the ablation of the adenoid. The use of SUSI did not have any impact on the duration of the operation or intra-operative and postoperative haemorrhage rates. Overall, the general consensus was that SUSI were as functional and safe as conventional re-usable instruments. A summary of the results is given in Table 3

Discussion

BBraun designed disposable adenotonsillectomy equipment, which, it was hoped, would meet the standards expected by UK surgeons. The equipment was made of a high-quality polymer rather than steel, which is easy to use, safe for patients, and cost effective. Some are close copies of existing instruments, for example, the knot pusher, Gwyn-Evans dissector and

Table 3 Summary of rating of SUSI by surgeon compared with re-usable steel instruments, in descending order of frequency of use

	Total used	Phase I			Phase II		
		No. used	Worse (%)	Same/better (%)	No. used	Worse (%)	Same/better (%)
Bipolar forceps	166	78	77	23	88	15	85
Dennis-Browne forceps	165	75	31	69	90	17	83
Boyle-Davis gag/blade	163	73	58	42	90	29	71
Draffin rods	152	74	41	59	78	22	78
Pillar retractor	135	59	14	86	76	5	95
Scissors	100	49	24	76	51	18	82
Gwyn-Evans dissector	66	32	18	82	34	18	82
Adenoid curette	24	11	55	45	13	15	85
No. of instruments used	971	451			520		

Where 15 or less instruments were used these have not been listed here.

Draffin rods. Others, including the Boyle-Davis gag and bipolar diathermy, are an evolution of standard instruments. The Boyle-Davis gag could not be directly copied as the polymer used is not strong enough for the forces involved. A more rigid circular structure was, therefore, designed.

The manufacturers maintain that the instruments are environmentally friendly in terms of incineration and disposal, and meet all relevant UK and European legislation. A prospective multicentre audit evaluated these instruments. Each instrument was individually scored in terms of functionality compared to more familiar, conventional, re-usable equipment by surgeons of all grades of experience. There is no data for the functionality rate of re-usable instruments but it is likely to be negligible as any complaints, once rectified, would be expected to be functional for the full life-span of the instruments. The surgeons' experience with particular instruments was recorded in order to account for the learning curve; some instruments, although perfectly functional, would score poorly if it were not the one the surgeon customarily used (for example, a Dennis-Browne used rather than a Luc's forceps).

The first cycle was successful in highlighting specific problems with the equipment which were generally felt by all the surgeons involved; in particular, the assessment indicated shortcomings in the Boyle-Davis gag, Draffin rods and bipolar diathermy. Of surgeons, 60.8% found the Boyle-Davis gag worse, 39.7% found the Draffin rods worse, and 75% found the bipolar forceps worse than disposable equipment. The Boyle-Davis gag framework was too bulky and, at times, it was rendered stiff from excessive friction between the blade and gag. It was also difficult to use in children under 15 kg. The bipolar forceps had too much

bare metal exposed and the point of contact of the bipolar diathermy forceps tips was not precise, often scissoring and making it difficult to perform a satisfactory operation. The forceps' tips opened under pressure and were not robust enough to perform a dissection. BBraun was quick to act on these findings and modify the equipment accordingly. The tonsillar gag was made suppler and the Draffin rods were shortened. The bipolar forceps were modified to be more precise with 1.5-mm tips, limiting the amount of bare metal showing to reduce unwanted thermal damage. The first cycle was a surveillance system, which enabled problems to be identified, understood and rectified. These problems were with the manufacturer's approved design rather than deviations from the approved design.

The second cycle evaluated the updated equipment and, on closure of the audit loop, it was generally agreed that all the new instruments were easy to use and served the surgeon well in performing adenotonsillectomy. In particular, 20.7% of the surgeons felt the bipolar forceps were better than re-usable equipment.

In the first cycle, the postoperative primary haemorrhage rate was 3.5%. The postoperative secondary haemorrhage rate was 3.5%, which was comparable to that reported in the national prospective tonsillectomy audit of 11,796 patients.⁵ In the second cycle, there were no reported postoperative haemorrhages. These results corroborate the findings of Montague *et al.*¹⁰ who carried out a prospective audit of 271 children undergoing tonsillectomy with either disposable or re-usable equipment; this study concluded that there was no statistically significant difference in postoperative haemorrhage rates between the two types of equipment. We can conclude that this particular type of disposable

equipment has met the essential safety requirements. However, this alone does not necessarily indicate if the instruments are free of problems.

Disapproval of individual instruments may be due to instrument failure or because of a particular surgeon's unhappiness although the instrument may not deviate from the manufacturer's agreed design. From the outset of this inquiry, there were perceptual problems with regard to disposable instruments, as some surgeons associated 'disposable' with poor quality. A surgeon's acceptance of surgical instruments may not wholly depend on simply the use of functional equipment but also what they are familiar with. Their expectations, hence, reflect their previous experience with re-usable instruments. Perhaps more junior surgeons such as SHOs who start with disposable equipment are less critical and adapt better to SUSI. The next generation of surgeons may find using SUSI more acceptable. Although SUSI aim to emulate traditional re-usable instruments, the wider goal is to produce acceptable equipment consistent in both form and function in large quantities. Re-usable equipment, which has problems, can be identified by theatre nurses, sterilisation services and can be repaired before use. In contrast, with disposable equipment, after dispatch fully packaged to hospitals from the manufacturer, the first instance a piece of equipment being recognised as having a problem is when the theatre nurse opens the packaging and the surgeon first uses it.

The second audit cycle indicated that, in general, surgeons found that all the disposable instruments to be as good as, or better than, existing ones. Because the majority of surgeons normally used re-usable metallic instruments, they were initially unaccustomed to using SUSI; but, after a period of customisation, they noticed little difference between kinds. Compared to conventional metal instruments, SUSI caused no increased intra- and postoperative haemorrhage risk, the duration of operation was similar, no remarks suggesting excessive postoperative pain were made, and the duration of postoperative hospital stay was the same. A small minority of surgeons found disposable instruments difficult to use, however; after using them a few times, they reverted back to re-usable equipment.

This prospective audit may be affected by a number of biases and, as a consequence, its results may fail to reveal other problems associated with disposable instruments. First, the surgeons' comparison of disposable instruments with the conventional re-usable variety is not randomised. Second, although the design modifications made to the Boyle-Davis gag showed a marked improvement, the instrument remained far from perfect. Of surgeons, 31.4% still felt that the Boyle-Davis gag was still harder to use. The Boyle-Davis gag made it harder for the surgeon to palpate the adenoid.

Third, our audit results are based on reports on participating departments, two of which are tertiary referral cen-

tres. Some patients with secondary haemorrhages may have gone to other district general hospitals for treatment and, as a consequence, the rates might have been under-reported, especially in those patients not returning to theatre.

The UK Department of Health allocated £200 million to modernise NHS decontamination procedures; the introduction of single-use instruments for tonsil surgery cost £25 million per annum.⁷ Cost effectiveness is outside the scope of this assessment. However, as the audit demonstrates that an average surgeon uses 7 or 8 individual pieces of disposable equipment rather than opening an entire kit, the cost of SUSI can be estimated. Calculating the cost of re-usable instruments is more difficult, as costs vary from hospital to hospital; the price of conventional re-usable equipment includes costs of production, sterilisation, transportation, maintaining trace-ability records, servicing, allowance for depreciation as well as costs of labour and time of staff involved. That considered, the cost of SUSI is roughly on a par with re-usable instruments.

Conclusions

ENT surgery is the first specialty to implement disposable equipment for routine operations involving lymphoid tissue, but expansion to other surgical specialties is inevitable. Certainly, the UK Department of Health is already considering introducing single-use surgical equipment to other surgical disciplines (such as neurosurgery), which deal with tissue that might harbour the prion. If disposable instruments are of a sufficiently high standard, they can be used in other disciplines to avoid the cross-infection of highly virulent or life-threatening illnesses such as HIV, and hepatitis B and C. The future of surgery lies in disposable instruments, which will obviate iatrogenic cross-infection. SUSI will develop to meet the changing demands of our surgical practice. As surgeons become increasingly familiar with SUSI, they will be recognised as a safe and a surgically acceptable alternative to reusable instruments.

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Declaration

Mr P O'Flynn assisted with the development of SUSI whilst seconded to the Raven Department of Education of The Royal College of Surgeons of England. BBraun the

manufacturer of SUSI sponsored this post. Mr O'Flynn has no financial interest in BBraun or this product. The instruments were provided free of charge during the assessment period.

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APPENDIX 1

Information on the audit form that was recorded by each surgeon

Grade of doctor
Age and gender of patient
Usual equipment used
SUSI cases (personal series)
Indications for tonsillectomy
Specific type of SUSI used
Assessment of individual SUSI
Suggestion on how to improve SUSI
Postoperative bleeding and management required