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Effect of disposable instruments on paediatric post-tonsillectomy haemorrhage rates

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Abstract

Background: A government directive aiming to minimise the theoretical risk of acquiring variant Creutzfeld–Jacob Disease (vCJD) from reusable instruments leads to tonsillectomy with disposable instruments becoming standard practice in the UK during 2001. A perceived increase in post-tonsillectomy haemorrhage followed soon after implementation of the directive. *Objective*: To determine if the introduction of disposable instruments is associated with a statistically significant change in post-tonsillectomy haemorrhage rates in children. *Methods*: A prospective audit of paediatric tonsillectomy with reusable instruments ($n=156$) had been undertaken (November 1999–November 2000). All children undergoing tonsillectomy with disposable instruments ($n=115$) were also studied prospectively (August 2001–December 2001) allowing the reactionary and secondary post-tonsillectomy haemorrhage rates for the two study periods to be compared. We hypothesised no difference in haemorrhage rates between reusable and disposable instruments. Statistical significance was calculated using Fisher's exact test and confidence intervals were established for the differences between study groups. *Results*: Cold dissection was undertaken in 62 children with reusable instruments and in 76 children with disposable instruments with secondary haemorrhage rates of 3.2% ($n=2$) and 2.6% ($n=2$), respectively. Bipolar diathermy dissection was undertaken in 94 children with reusable instruments and in 39 children with disposable instruments with respective secondary haemorrhage rates of 6.4% ($n=6$) and 12.8% ($n=5$). No reactionary haemorrhages occurred with reusable or disposable instruments. No difference was found in the overall secondary haemorrhage rate between reusable and disposable instruments ($p=0.93$, Diff 1.0% (95% CI; −7.4 to +4.6)). *Conclusions*: The introduction of disposable instruments has not produced a statistically significant increase in paediatric post-tonsillectomy haemorrhage rates in our centre.

Keywords: Tonsillectomy; Haemorrhage; Disposable instruments

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1. Introduction

In January 2001, the Department of Health in the United Kingdom targeted tonsil and adenoid surgery for the compulsory introduction of disposable instruments. The aim was to minimise the theoretical risk of acquiring variant Creutzfeld–Jacob Disease (vCJD). This government directive was estimated to cost £25 million per annum [1]. The Spongiform Encephalopathy Advisory Committee (SEAC) advised the government on this issue after a detailed risk assessment had been undertaken [2].

Disposable instrumentation came into use from August 1st 2001 in our centre. Its introduction was accompanied by a perceived increase in the rate of secondary post-tonsillectomy haemorrhage at a number of UK centres. Disposable electrosurgical diathermy forceps were implicated in a Medical Devices Agency hazard warning [3]. It was thought that the increased diathermy effect of a single-use instrument resulted in greater than normal collateral tissue damage with greater sloughing of the primary eschar 7 to 10 days post-operatively. Despite their suspension from routine use reports of increased haemorrhage rates with disposable instruments continued. This lead to genuine fears over patient safety compared with a theoretical risk of vCJD transmission.

The aim of this study is to determine if the introduction of disposable instruments is associated with a statistically significant increase in paediatric post-tonsillectomy haemorrhage rates.

2. Materials and methods

This is a prospective comparative study of all children (14 years and under) undergoing bilateral tonsillectomy during two study periods in a university department of Otolaryngology. A prospective audit of paediatric tonsillectomy with reusable instruments ($n = 156$) had been undertaken during November 1999–November 2000. All children undergoing tonsillectomy with disposable instruments ($n = 115$) were also studied prospectively (August 2001–December 2001) allowing the reactionary and secondary post-tonsillectomy haemorrhage rates for the two study periods to be compared.

Tonsillectomy was performed by either cold dissection (CD) or bipolar diathermy dissection (BPD) according to surgeon preference. Haemostasis was secured with bipolar diathermy alone or with a combination of ties and bipolar diathermy in the 'cold' procedures. All tonsillectomies were performed as inpatient procedures under general anaesthesia. All grades of surgeon working in the department participated during both

Table 1
Incidence of post-tonsillectomy haemorrhage in children with reusable instruments (November 1999–November 2000)

	Reactionary haemorrhage (%)	Secondary haemorrhage (%)
CD $n = 62$	0 (0)	2 (3.2)
BPD $n = 94$	0 (0)	6 (6.4)
Total $n = 156$	0 (0)	8 (5.1)

Table 2
Incidence of post-tonsillectomy haemorrhage in children with disposable instruments (August 2001–December 2001)

	Reactionary haemorrhage (%)	Secondary haemorrhage (%)
CD $n=76$	0 (0)	2 (2.6)
BPD $n=39$	0 (0)	5 (12.8)
Total $n=115$	0 (0)	7 (6.1)

study periods. Antibiotics were not administered postoperatively. It is departmental policy to admit all children presenting with secondary haemorrhage irrespective of its severity. The occurrence of reactionary or secondary haemorrhage and their timing were recorded post-operatively. Post-operative haemorrhage was defined as reactionary if within 24 h of surgery and secondary when between 7 and 10 days after surgery.

We hypothesised no difference in post-tonsillectomy haemorrhage rates for reusable and disposable instruments. Fisher's exact test was used for statistical analysis with a p value <0.05 deemed significant. 95% confidence intervals were established for the differences observed between the two study periods.

3. Results

A total of 156 children underwent tonsillectomy with reusable instruments and 115 children with disposable instruments. No reactionary haemorrhages occurred with reusable or disposable instruments irrespective of the method of dissection. Cold dissection was undertaken in 62 children with reusable instruments and in 76 children with disposable instruments with secondary haemorrhage rates of 3.2% ($n=2$) and 2.6% ($n=2$), respectively ($p=1.00$; Diff 0.6% (95% CI; -6.3 to $+8.6$)). Bipolar diathermy dissection was undertaken in 94 children with reusable instruments and in 39 children with disposable instruments with respective secondary haemorrhage rates of 6.4% ($n=6$) and 12.8% ($n=5$) ($p=0.37$; Diff 6.4% (95% CI; -20.7 to $+3.5$)). No difference was found in the overall secondary haemorrhage rate between reusable and disposable instruments ($p=0.93$, Diff 1.0% (95% CI; -7.4 to $+4.6$)). These results are summarised in Tables 1 and 2. The difference between haemorrhage rates for surgeons of different levels of experience was also examined but no statistical significance was found for tonsillectomy using reusable or disposable instruments (X^2 test $p>0.1$).

4. Discussion

Tonsillectomy was an operation targeted by the department of health in the United Kingdom for the introduction of disposable instruments for several reasons. Firstly lymphoid tissue such as the tonsils is known to harbour relatively high concentrations of the transmissible prion agent in the very early stages of vCJD [4]. Tonsillectomy also involves a discrete set of instruments. Of particular relevance to this study is the fact that

tonsillectomy, with or without adenoidectomy, is the most common operation performed in children today. It is the paediatric population in whom the potential impact of iatrogenic transmission of the disease is greatest given a child's estimated further life expectancy of 65 years and a possible incubation period of several decades for the condition [5].

Dissection tonsillectomy is the most commonly employed surgical technique in the United Kingdom [6]. The cold dissection and bipolar diathermy dissection techniques have both been previously described in the literature [7,8].

We found no statistically significant difference in the reactionary and secondary post-tonsillectomy haemorrhage rates in the children studied when reusable and disposable instruments were compared. The wider confidence interval observed when tonsillectomy was performed by bipolar diathermy dissection is indicative of the relatively small number of children undergoing tonsillectomy by that particular dissection technique with disposable instruments. When the overall post-tonsillectomy haemorrhage rates are compared however, the 95% confidence interval is relatively narrow.

The government directive leading to the mandatory use of disposable instruments nationwide from the outset meant that there was no provision for a pilot study using the new instrumentation. For this reason and because of a nationwide moratorium on further tonsil surgery with reusable instruments, randomisation of cases to tonsillectomy with reusable or disposable instruments was not possible in this study.

5. Conclusion

The introduction of disposable instruments has not produced a statistically significant increase in paediatric post-tonsillectomy haemorrhage rates in our centre.

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