Randomized trial

Randomized clinical trial of suction *versus* standard clearance of the diathermy plume

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Background: **Diathermy smoke contains complex hydrocarbons and organic material, and may contain viable tumour cells or viral particles. These particles measure from 0·05 to more than 25 μm, and long-term exposure to such particles may have adverse effects on health. This study investigated whether a suction clearance device reduces the amount of smoke reaching the surgeon's mask.**
Methods: **This was a randomized clinical trial in which subjects were randomized to standard diathermy equipment (group 1) or a diathermy smoke extraction system (group 2). All patients underwent thyroid or parathyroid surgery with standard anterior cervical collar incision and division of the strap muscles. The difference in the amount of smoke reaching the level of the operator's mask was measured by means of an aerosol monitor.**
Results: **Fifteen patients were randomized to each group. The mean amount of smoke detected at the level of the operator's mask was 0·137 mg/m^3 in group 1 and 0·012 mg/m^3 in group 2 ($P < 0·001$). The maximum amount detected was 2·411 and 0·255 mg/m^3 respectively ($P < 0·001$). There were no significant differences between the groups in terms of incision time or background particles measured before and after surgery. There was no correlation between gland weight and incision time or amount of smoke detected.**
Conclusion: **Suction clearance of the diathermy plume resulted in a significant reduction in the amount of smoke reaching the level of the operator's mask. Although the risk of diathermy smoke inhalation is currently unknown, use of such a system appears advisable.**

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Introduction

Operating theatre staff are exposed to 'surgical smoke' when using diathermy or laser. Surgical smoke contains hazardous chemicals[1], exposure to which may cause symptoms such as airway inflammation, coughing, headache, tearing, nausea and vomiting. More recent evidence that the smoke may carry viable cells, tumour cells and virus particles has prompted the development of methods to clear the smoke plume.

In 1994 the Australian Standard[2] addressing the issue of airborne contaminants in the workplace was published (updated 1998), outlining the need to confine and contain the contaminants generated by diathermy during surgical procedures. The Australian College of Operating Room Nurses Ltd (ACORN) standards[3] also emphasize this need. In the UK, the updated Control of Substances Hazardous to Health (COSHH) regulations[4] came into force in November 2002. These regulations will implement the health requirements of the European Union's Chemical Agents Directive (CAD) that are not already set out in British legislation. The regulations require employers to assess risks to health arising from exposure to hazardous substances; prevent or adequately control exposure; ensure that control measures are used, maintained, examined and tested; in some circumstances monitor exposure and carry out appropriate health surveillance; and inform, instruct and train employees.

The aim of this study was to evaluate the effectiveness of a diathermy smoke extraction system (Lina Grey Shark™; EMT Healthcare, Warriewood, New South Wales, Australia) in clearing the diathermy plume compared with

standard diathermy, by measuring the amount of smoke reaching the surgeon's mask, in a randomized clinical trial.

Patients and methods

The protocol for the study was approved by the Northern Sydney Health Human Research Ethics Committee. Thirty consecutive patients scheduled for standard anterior cervical collar incision were recruited and randomized to standard diathermy or the diathermy smoke extraction system. Exclusion criteria included refusal of consent, previous neck surgery, a history of irradiation or operation that required non-standard incision. All patients were aged 18 years or older. All patients were provided with a written information sheet and gave written informed consent.

Data regarding smoke were collected up to division of the strap muscles, thereby providing a standardized and reproducible measure[5] of diathermy smoke production. The standard approach to the thyroid involved an 8-cm incision through the skin, superficial fascia and the platysma. Diathermy was then used to ensure haemostasis, raise the subplatysmal flaps and divide the strap muscles. A diathermy setting of 30 W (fulgarate) was used for both groups.

The suction extraction system consisted of a standard size diathermy pencil with a 'shark mouth' opening on its distal ventral surface. This opening communicated with suction tubing on the end of the pencil. The plume was directed into the mouth by a removable plastic sleeve. The plume was then directed into a standard suction canister, through a ClearFlow™ filter (Surgin, Tustin, California, USA) and into the wall suction unit. The suction rate was set at 30 l/min.

The main outcome measure was the amount of smoke reaching the level of the surgeon's mask. The amount of smoke was measured using the DustTrak Aerosol Monitor™ (TSI, St Paul, Minnesota, USA; supplied by Kenelec Scientific, North Ryde, New South Wales, Australia), a portable laser photometer that detected particles in the range 0·1–10 μm. The photometer continuously sampled the air and gave a reading once per second. At the end of a given measurement period, a data summary with mean, minimum and maximum particle readings in milligrams per cubic metre was obtained. The duration of sampling was also recorded. The photometer was adjusted to zero before each day's measurements and then positioned behind the surgeon, with the sampling port secured at the suprasternal notch, clear of the surgical gown. Baseline, intraoperative (up to division of the strap muscles) and postoperative measurements were recorded. The baseline measurements were taken before the patient entered the operating theatre, and the postoperative measurement was taken just after the patient was taken to the recovery room.

Data were entered into a computerized database and subsequent statistical analysis was performed with SPSS® software (SPSS, Chicago, Illinois, USA) using Mann–Whitney *U* tests for comparison between groups.

Results

Thirty patients were entered into the study over a 2-month period from November 2002 and randomized to operation with standard diathermy (group 1; $n = 15$) or with the diathermy smoke extraction system (group 2; $n = 15$). Indications for surgery are listed in *Table 1*. The mean age of patients was 47 (range 23–77) years. There were 28 women and two men. The mean time to division of the strap muscles was 15 (8–22) min in group 1 and 18 (range 9–30) min in group 2. The difference was not significant.

Use of the diathermy smoke extraction system resulted in a significant reduction in both the mean and the maximum amount of smoke detected at the level of the operator's mask. The mean amount detected was 0·137 (95 per cent confidence interval (c.i.) 0·063 to 0·211) mg/m^3 in group 1 and 0·012 (95 per cent c.i. 0·005 to 0·019) mg/m^3 in group 2 ($P < 0·001$) (*Fig. 1*). The maximum amount detected was

Table 1 Indications for surgery

	Standard diathermy ($n = 15$)	Smoke extraction ($n = 15$)
Thyroid malignancy	7	3
Multinodular goitre	5	8
Single nodule	2	1
Grave's disease	1	2
Parathyroid adenoma	0	1

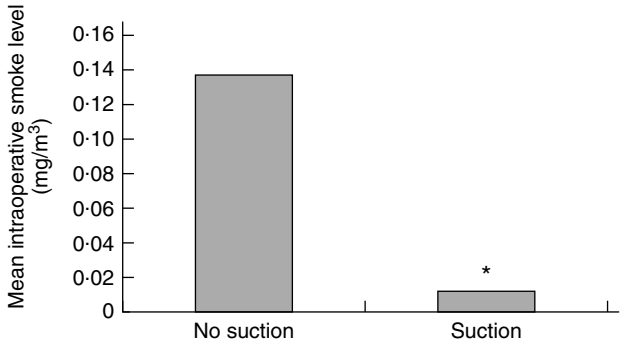

Fig. 1 Mean intraoperative smoke levels. *$P < 0·001$ *versus* no suction (Mann–Whitney *U* test)

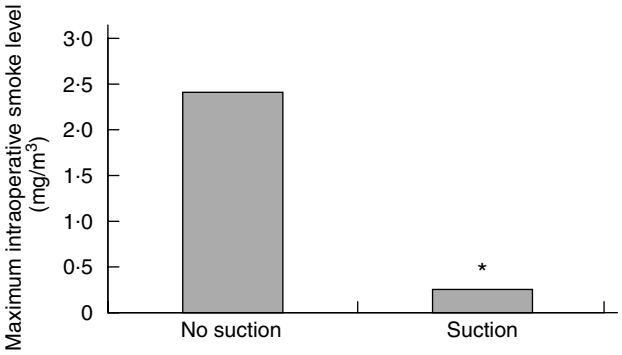

Fig. 2 Maximum intraoperative smoke levels. *$P < 0{\cdot}001$ *versus* no suction (Mann–Whitney U test)

2·411 (95 per cent c.i. 0·817 to 4·004) and 0·255 (95 per cent c.i. 0·064 to 0·445) mg/m^3 respectively ($P < 0{\cdot}001$) (*Fig. 2*). There was no correlation between gland weight and amount of smoke or time to division of the strap muscles. There was no significant difference between the baseline and postoperative readings. There were no adverse events related to the extraction system over the course of the trial.

Discussion

There are many risks to operating room staff and patients in the practice of surgery. Several groups have studied electrosurgery smoke and the dissemination of contaminants, but no published study has assessed the amount of smoke exposure to the surgeon, and methods to reduce it.

It is accepted that electrosurgery smoke may be hazardous to patients and staff. The surgical team and scrub nurse are probably at greatest risk because of frequent exposure to the diathermy plume. In addition to the known potentially mutagenic agents within electrosurgery smoke, infectious agents such as prions may be present. The burning of proteins and lipids during electrosurgery liberates byproducts such as complex hydrocarbons, some of which are known carcinogens[1]. Carbon monoxide is also produced and may cause hypoxic stress in healthy patients owing to its high affinity for haemoglobin. Reduced oxygen-carrying capacity of the blood may impair cardiovascular function in patients with pre-existing cardiovascular disease[6].

The transmission of viruses or other infectious agents is one of the most topical, theoretical complications of any surgical intervention. There is justifiable concern regarding the presence of viable virus particles in electrocautery smoke. Studies have shown a higher incidence of nasopharyngeal lesions in carbon dioxide laser surgeons[7] and that human immunodeficiency virus (HIV) DNA in carbon dioxide laser smoke may remain viable for 14 days[8]. There is strong evidence for the presence of viable virus particles in electrocautery smoke over a range of diathermy power settings[8,9]. HIV, human papillomavirus, mycobacteria, and hepatitis B and C are all in the particle size range 0·04–0·18 μm, and may all be carried in the respirable aerosol.

The American Conference of Governmental Hygienists, the International Standards Organisation and the Comité Européen de Normalisation have defined a respirable aerosol as containing particles of 4·5 μm or smaller[10]. Such respirable aerosol or 'lung damaging dust' has been shown to be present in electrosurgery smoke[11] and experimental studies have shown that repeated exposure to such smoke results in pathological changes to the rat lung[12,13]. It is recognized that surgical masks do not provide complete protection when submicrometre-sized aerosol is present[14,15].

The Australian Standard[2] dealing with the removal of airborne contaminants in surgery was published in 1994, and updated in 1998. The recommendations from the Standard were supported by the ACORN Standard A27[3], amended in December 2000. Both organizations recommended that efforts should be directed towards the controlled removal of the surgical plume. In Europe and the UK, the health requirements defined by the COSHH and the CAD are aimed at protecting the health and safety of workers from chemical and biological agents.

Methods for extracting the diathermy plume include simply holding a suction device next to the diathermy probe. This is not a satisfactory long-term solution as it requires an experienced assistant so that the surgeon's view remains unimpeded, uses up one of the assistant's hands, is variable in its effectiveness and the waste product goes straight into the wall suction system. Smoke settles in the hospital pipework and builds up over time. Wall suction is also vented directly into the environment, with unknown consequences.

The Lina Grey Shark™ diathermy smoke extraction system resulted in a significant reduction in smoke reaching the surgeon's mask. The ClearFlow™ filter clears more than 99·9 per cent of particles down to 0·02 μm, thus ensuring that hazardous products are not carried into the environment. There were a number of advantages and few disadvantages with the system. It was easy to set up, simple to operate and the pencil thickness was the same as that of a standard instrument making it comfortable in the hand. Clearing the plume improved vision in the operative field,

and there was a noticeable reduction in the characteristic diathermy smell. The weight of the suction tubing was a disadvantage but this problem was reduced by minimizing the slack in the length of tubing.

The potential risks to the surgeon and the surgical team of continued exposure to electrosurgery smoke have been documented. Although level I evidence of a causal link between diathermy smoke and disease will probably remain elusive, optimizing health and safety in the workplace is an ongoing goal in most institutions. In terms of surgical smoke there already exist Australian standards to be achieved, and UK regulations to be implemented. It would therefore appear prudent to make surgical smoke extraction systems mandatory.

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