The Value of Suction Wound Drain after Carotid and Femoral Artery Surgery: A Randomised Trial Using Duplex Assessment of the Volume of Post-operative Haematoma

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Background. The use of vacuum suction drains after carotid endarterectomy (CEA) and groin dissection for arterial reconstruction surgery remains controversial. A large multicentre prospective randomised trial would be needed to show any difference if clinical end points (infection and haematoma) are used. Therefore, we conducted a study to evaluate the value of wound drainage using accurate duplex measurement of haematoma expecting a 25% difference in volume between drained and non-drained wounds.

Patients and methods. Seventy consecutive patients undergoing CEA and 73 patients who underwent 106 groins dissection were separately and blindly randomised into two groups: group (a) with wound drain and group (b) without wound drain. A duplex scan was carried out post-operatively to document the presence and volume of any wound haematoma.

Results. The majority of wounds did not show any evidence of collections. In the CEA patients duplex scan revealed wound haematoma in 8 patients with a median volume of 25 ml (5–65) in group (a) in comparison to 7 wound haematomas 31 ml (3–72) in group (b). Median suction drain drainage was 42 ml (10–120) when used. There was no significant difference between the two groups. Three patients 4.3% (two from the drain group) underwent evacuation of haematoma post-operatively.

In the groin dissection patients most of the documented collections were trivial. Ultrasound scans showed 21 collections (20%), of these 7 (34%) were in group (a) and 14 (66%) were in group (b). There was no significant difference in wound collections between the two groups (p = 0.28). Only 5 collections (75%) exceeded 10 ml, three of them were in the drain group. One patient (1%), who did not have a drain, developed a wound collection, which needed re-exploration. When a drain was used the median drainage was 64.5 ml (range 10–220).

Conclusion. These results based on accurate measurement of wound collection suggest that there is no benefit in terms of reduction of the volume of haematoma on wound drainage after CEA or arterial reconstruction surgery involving the groin. A selective policy of use of drainage is therefore recommended.

Keywords: Carotid endarterectomy; Wound drain; Haematoma; Duplex ultrasound; Wound infection.

Introduction

It has been a routine practice in many vascular centres to drain wounds following carotid endarterectomy (CEA) and groin dissections for arterial bypass surgery involving the femoral arteries.¹ The rationale behind the use of drains is to prevent fluid collections, which in the neck might cause respiratory complications or become secondarily infected; thus decreasing the rate of wound infection and potentially the disastrous complication of graft infection.² However, the role of drains has been questioned in surgical practice, especially after introduction of guided drainage for any residual collections.³ The routine use of drains has been discontinued in many surgical procedures where drains were previously used.⁴–⁶ On the other hand and despite some controversy, drains are proven to be valuable after mastectomies and breast reconstruction.⁷,⁸

The incidence of wound haematoma after CEA is reported to range between 0.8 and 12% with an associated increase in both morbidity and mortality.⁹,¹⁰
Non-reversal of heparin, intra-operative hypertension and carotid shunt placement were multivariate predictors of post CEA haematoma formation.\textsuperscript{10} Currently the trend is to use vacuum suction drains after CEA, but the efficacy of drains in neck surgery is controversial. Drains have not been found to be effective in reducing haematoma formation after thyroidectomy/parathyroidectomy and oesophageal surgery.\textsuperscript{11–13} Only large size drains have been shown to have some benefits after carotid surgery.\textsuperscript{14}

There are no controlled studies prior to 1989 to evaluate the use of drains in wounds involving the femoral arteries. Since then two studies have been published using clinical end points neither showing any benefit from drain use.\textsuperscript{15,16} The studies included 100 and 127 patients, respectively, and since wound complications are relatively rare it was difficult with these small numbers to show any significant difference between the two randomised groups.

Any prospective comparison of drain versus no drain based on clinical end points such as infection and haematoma would need a very large number of patients, because of the low incidence of these complications.

We therefore conducted a prospective randomised study to evaluate the efficacy of wound drains after CEA and groin dissection based on accurately measured wound haematoma using duplex scanning.

**Patients and Methods**

The Ethical Committee of the Royal Free Hospital NHS Trust approved the trials and informed consent was obtained. The trials were prospective and randomisation was to drain or no drain. To implement this trial we used sealed envelopes containing ‘drain’ or ‘no drain’. An envelope was then drawn for each patient thus deciding whether or not to use a drain. Randomisation was immediately prior to wound closure once haemostasis was achieved. When randomised to drain a 10F suction Redivac drain (wound drainage system 600, Medinorm) was placed alongside the common carotid artery or the femoral vessels and brought out through a separate stab incision medial and below the main wound. All wounds were closed in layers using continuous 2/0 vicryl and 3/0 subcuticular vicryl suture.

The time for the ultrasound was chosen after a small lead—in study indicated 2 and 5 days to be the optimum time to detect fluid collections should they occur after carotid and groin surgery, respectively.

An accredited vascular technologist and a senior radiologist with a special interest in ultrasonography performed all scans. The assessment of the volume of the haematoma was calculated by measuring its maximum dimensions (in three planes). The data including the ultrasound reports were collected on a standard data sheet, which was analysed by the principal author. The sonographer could not be blinded about the use of drain when performing the measurements because of the visibility of the drain site which could not be covered up.

Validation of the method: we validated this methodology in our centre before starting the trial by doing a small pilot study. The inter-observer and intra-observer error was <5%. However, there were difficulties assessing the size of the haematoma in some situation, especially where there was diffuse spread under the skin giving extensive bruising.

Corrected Chi-square testing test was used to assess any significant difference between the two groups. The results are expressed as median and range.

**Trial 1**

Included 70 consecutive patients undergoing CEA performed between 1999 and 2002 (Table 1 summarised patients profile). Most procedures were done under general anaesthesia (53 patients). Recently local anaesthesia with nerve block was used in (17 patients) either because the patients were considered unfit (high risk) for general anaesthesia or as a part of the GALA trial, which compared local to general anaesthesia for carotid surgery.

The indications for CEA were symptomatic carotid artery stenosis (53 patients) or as part of the Asymptomatic Carotid Artery Stenosis Trial (ACST) in (17 patients).

Skin crease incision was used. Once the carotid artery was dissected 5000 U of heparin was given before clamping, heparin reversal was not used in any of the patients.

Shunting was used selectively (according to stump pressure $<50$ mmHg and TCD continuous monitoring) in 17 patients, 16 patients of them were under GA. Dacron patch closure was used selectively when the distal ICA diameter was $<5$ mm in 49 patients. Our policy was not to stop aspirin therapy in the perioperative period. However, Clopidogrel treatment was stopped 2 weeks prior to CEA.

After completion of CEA and achievement of satisfactory haemostasis, the patients were randomised into two groups; group (a) with suction wound drain and group (b) without wound drain. The drain, if used, was removed on the second post-operative
day and the volume of fluid drained was recorded. Duplex scan was performed on the third postoperative day to detect and measure any haematoma.

**Trial 2**

A total of 73 consecutive patients had 106 groins randomised after groin arterial surgery. (Patients profile is summarised in Table 2.) A standard operative procedure was followed in all cases. A longitudinal incision is used with the groin tissue being ligated and divided. 49 groins were randomised to drain (group a) and 57 to no drain (group b). Randomisation was to drain or no drain in patients who underwent unilateral procedures. In patients having a bilateral procedures one side was randomised to have a drain and the other side was not drained. Drains were removed when producing less than 30 ml of fluid in 24 h. An ultrasound of the operated groin was performed on the fifth post-operative day. The presence and the volume of any wound collections were recorded.

**Results**

**Trial 1**

Of the 70 participants, 34 patients were randomised to group (a) with a drain and 36 to group (b) without a drain. The demographic and clinical characteristics of these patients are shown in (Table 1). There was no significant difference in age or sex distribution between the two groups. There was no correlation found between the presence of clinical or duplex detected haematoma and the type of anaesthesia, the use of shunts, symptomatic stenosis or the use of patches.

Median volume collected in group (a) from drains was 42 ml (range 10–120 ml). Duplex revealed 8 wound collections in the drain group, median volume of haematoma being 25 ml (range 5–65 ml). In group (b), duplex detected 7 haematomas with median volume of collection being 31 ml (range 3–72 ml); there was no significant difference between the two groups (Table 3). The difference was only significant in favour of no drainage when the drain contents were added to the size of wound haematoma ($p < 0.001$).

Three patients developed haematoma; 4.3%; two patients in the drain group; requiring evacuation for increased neck swelling to prevent respiratory complications. The same surgeon who performed the CEA explored the wound haematoma and at this stage the surgeon was not blinded about the presence of wound drain. One patient in group (a) developed a superficial wound infection and one from group (b) developed extensive neck and upper chest wall bruising ultrasound duplex confirmed underlying haematoma, both did not require any treatment.

Repeated duplex after 6 weeks did not show any significant difference in age or sex distribution between the two groups. There was no correlation found between the presence of clinical or duplex detected haematoma and the type of anaesthesia, the use of shunts, symptomatic stenosis or the use of patches.

**Table 1. Profile of the patients ($n = 70$) included in trial 1 (CEA) study and the incidence of haematomas**

| Total procedures No. | No drain | | Drain | |
|---------------------|---------|---------------------|-------|
| Patients no.        | 36      | 8$^a$              | 34    | 10$^a$ |
| Age (years), median (range) | 74 (56–81) | 6/2                | 75 (58–82) | 8/2 |
| Sex M/F             | 25/11   | 3$^a$              | 27/7  | 7$^a$ |
| Indications for CEA symptomatic/ asymptomatic | 26/10 | 6/2 | 25/9 | 6/2 |
| Shunt used          | 10      | 7                  | 7     | 2$^a$ |
| Patch               | 26      | 8                  | 23    | 7$^a$ |
| GA/LA               | 28/8    | 8                  | 25/9  | 9 |

$^a$ One clinically significant haematoma.

$^b$ Two clinically significant haematomas.

**Table 2. Demographics trial 2 (groin) patients**

| Patients no. | 73 |
| Sex M/F          | 40:33 |
| Age median (range) | 72 years (44–90) |
| No. of procedures | 106 |
| Endarterectomy procedures | 86 (81%) |

**Table 3. Profile of wound complications after CEA**

<table>
<thead>
<tr>
<th>Wounds no.</th>
<th>No drain</th>
<th>Drain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haematoma no. (%)</td>
<td>8 (53%)</td>
<td>7 (47%)$^a$</td>
</tr>
<tr>
<td>Significant haematomas</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Volume of collection, ml</td>
<td>25 (5–65)</td>
<td>31 (3–72)$^a$</td>
</tr>
<tr>
<td>Volume in the drain median (range) ml</td>
<td>Not applicable</td>
<td>42 (10–120)</td>
</tr>
</tbody>
</table>

$^a$ Not significant.
residual haematomas or any difference between the two groups regarding residual stenosis.

**Trial 2**

There were 21 fluid collections demonstrated by ultrasound in 106 wounds (20%). There was no ultrasound evidence of collection in 85 groins. Of these collections 14 were in the no drain group (66%) and 7 in the drain group (34%) (Table 4). This was not statistically significant (p = 0.28). Only five collections were graded as moderate–large exceeding 10 ml. Three of them occurred in the presence of a wound drain. The presence of fluid collection was unrelated to the type of graft used, i.e. vein or synthetic as 5/21 (23.6%) collections developed in cases where a vein graft had been used. This is almost identical to the overall proportion of vein grafts in the whole series 24/106 (22.6%). The median drainage volume (if a drain is used) was 64.5 (range 10–220) ml. The drain stayed for 2 days (range 1–5).

There were 14 wound complications in the series (Table 5). These were more common (9/14) in the group where no collection was detected than in the group (5/14) where there was a documented fluid collection. These results also did not reach statistical significance (p = 0.21). Wound complications occurred equally in the drain and no drain groups (7/14 each). Wound infections were treated successfully with antibiotics and wound dressing. Pseudomonas was grown from two wounds and *Staphylococcus aureus* from the other five wounds. In four patients treatment was initiated with antibiotics, but no pathogen was isolated. In the remaining three wounds there was either wound haematoma or a sterile lymph discharge. In 13 wounds the healing was complete on conservative treatment, but in one patient where pseudomonas was isolated, the case was complicated with late graft and suture line dehiscence infection 10 days post-operatively. This complication resulted in an above knee amputation despite urgent surgical intervention and occurred in a diabetic patient who did not have wound drainage.

The type of graft used was not related to the occurrence of complications as 5/14 (35.5%) complication happened in cases where a vein graft had been used. This is similar to the overall proportion of vein grafts in the whole series. Subgroup analysis of this data, e.g. examining the effect of diabetes, sex, age or obesity was not undertaken as the resultant groups would have been too small for meaningful comment.

**Discussion**

Wound drains can be painful and need special nursing experience and time to manage. Perhaps of greater clinical importance, drains might act as a portal of entry for bacteria to cause wound infections and of course cost money.\(^{16,17}\) Hospital stay is reported to be longer in patients with a drain.\(^{5}\) Moreover, there are reported complications associated with their use.\(^{18}\) Most surgeons do not practice ‘evidence-based medicine’ with regards to wound drainage.\(^{19}\) The routine use of drains after neck surgery has been questioned, as drains did not decrease the risk of wound complications.\(^{11–13}\) To justify their use we must demonstrate a logical basis for this use and show that they transfer some advantage to patients. The benefit of wound drainage in this context has not been clearly demonstrated before, but despite this the practice remains common.\(^{20}\)

The presence of clinical wound haematoma after CEA is frequently reported. Many predisposing factors may be involved.\(^{10}\) In order to prevent this complication, which may require urgent surgical evacuation to prevent respiratory complications; most surgeons use a vacuum suction drain in the wound. But even the routine use of drains does not prevent post-operative wound haematoma.

A review of the literature did not show any randomised study on the use of suction drains after carotid artery surgery. However, in a recent study, routine use of 10 F drains failed to prevent wound haematomas.\(^{6}\) The authors then discontinued the routine use of drain in a later series of patients, which then resulted in increased incidence of wound haematoma. The use of 14 F drains was then introduced in the latest series of patients, which resulted in a decrease in the incidence of wound haematoma. This study was a non-randomised and conducted in different time spans and so the results cannot be used to determine clinical practice.\(^{10}\)

There is close agreement between the two reported groin wound trials on the influence of wound drains on wound complications.\(^{15,16}\) The relationship between complications and drains in the three reported trials (including this trial) with a combined number of 333 groins randomised shows no difference in the incidence of complications between the drain and non-drain groups (p = 0.96).

Although the 4.3% incidence of wound haematoma after CEA needing surgical evacuation seems to be high, this may reflect the authors’ policy of not stopping aspirin therapy prior to the procedure. Moreover, it is similar to that reported in the literature.\(^{21}\)
Table 4. Profile of wound collections and the grafts used after groin surgery (trial 2)

<table>
<thead>
<tr>
<th></th>
<th>No drain</th>
<th>Drain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wounds no.</td>
<td>57</td>
<td>49</td>
</tr>
<tr>
<td>Haematoma no. (%)</td>
<td>14 (66%)</td>
<td>7 (34%)</td>
</tr>
<tr>
<td>(volume &gt; 10 ml)</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Volume of haematoma median (range)</td>
<td>7 (0–65)</td>
<td>6 (0–18)*</td>
</tr>
<tr>
<td>Volume in the drain median (range)</td>
<td>Not applicable</td>
<td>64.5 (10–220)</td>
</tr>
<tr>
<td>Vein graft</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Synthetic patch</td>
<td>44</td>
<td>38</td>
</tr>
</tbody>
</table>

*p = 0.28.

Most of the groin wounds in this study did not develop complications, as could be expected. Prior to this study the true incidence of fluid collection in groin wounds was unknown. Now we can see that this occurred only in <20% of wounds. Thus, for the majority of wounds there is no rational basis for drainage. Where fluid collections did occur in this study the majority were trivial. Most groin wound complications were minor and required only local wound treatment and antibiotics.

The relatively higher incidence of duplex detected wound collections in the two trials reflects the fact that most of these collections were clinically not apparent and so would only be detected by duplex ultrasound measurements. Also, these collections were inconsequential as in most patients, were clinically not detectable, and resolved spontaneously.

Wound complications were not significantly affected by wound drainage, nor were they related to the presence of fluid collections. Importantly, significant fluid collections were not prevented by the use of drains.

To our knowledge, this is the first study, which used duplex ultrasound to accurately measure the postoperative wound collection in vascular surgery. We have found that the use of drains failed to significantly decrease the risk of haematoma requiring surgical evacuation or amount of fluid collections. Although the sample size is small, the trials demonstrated that routine use of vacuum suction drains did not reduce the volume of wound haematomas and so cannot be recommended as a routine requirement of carotid or groin vascular procedures. Furthermore it confirms that wound haematoma is a minor problem with or without the use of a drain. Therefore, a policy of routine drainage is not justified.

References


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