Who needs a stapling device for haemorrhoidectomy, if one has the radiofrequency device?
Polson, Robert; Watson, Angus J M; Sunny, A; Sellars, H; Ramsay, G

Published in:
Coloproctology
Publication date:
2019
Publisher rights:
© The Author(s) 2019
The re-use license for this item is:
CC BY
The Document Version you have downloaded here is:
Publisher's PDF, also known as Version of record

The final published version is available direct from the publisher website at:
10.1007/s00053-019-00420-0

Link to author version on UHI Research Database

Citation for published version (APA):

General rights
Copyright and moral rights for the publications made accessible in the UHI Research Database are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights:

1) Users may download and print one copy of any publication from the UHI Research Database for the purpose of private study or research.
2) You may not further distribute the material or use it for any profit-making activity or commercial gain
3) You may freely distribute the URL identifying the publication in the UHI Research Database

Take down policy
If you believe that this document breaches copyright please contact us at RO@uhi.ac.uk providing details; we will remove access to the work immediately and investigate your claim.

Download date: 04. Apr. 2020
Conventional haemorrhoidectomies are often associated with postoperative pain and bleeding. More recent techniques such as stapled haemorrhoidopexy and radiofrequency haemorrhoidectomy aim to reduce these complications. We systematically compared the evidence on complications, outcomes, patient experiences and costs of these modern methods.

Haemorrhoidectomy is effective and widely used for symptomatic grade 3 and 4 haemorrhoidal disease [16]. Conventional excisional techniques include the Milligan–Morgan [10], Ferguson [6], and Parks procedures [12] performed with diathermy, scissors or scalpels. The most common problems are postoperative pain and bleeding. More recent techniques such as stapled haemorrhoidopexy (SH) and haemorrhoidectomy using a radiofrequency device (RFH) were developed to reduce these complications.

Herein, we aim to look at the evidence comparing SH to RFH with respect to complications, outcomes, patient experiences and costs.

Materials and methods

A literature review was performed using multiple databases: Ovid MEDLINE, CINAHL, SCOPUS, PROSPERO, Cochrane library, EMBASE, World of Knowledge and PubMed. The search strategy was tailored for each database and, where feasible, combined both MeSH terms and keywords. The three components of each search were haemorrhoids, radiofrequency (RF) or named devices and stapled, procedure for prolapse and haemorrhoids (PPH) or Longo procedure.

Following the initial searches, references were examined via the abstract. Studies containing primary outcome data or secondary analyses comparing SH with RFH were included and full texts retrieved. The relevance and completeness of the published data were reviewed. Studies with significant missing methodological information, outcome data or statistical analyses were subsequently excluded. The citations and references of included papers were searched for further relevant studies. Fig. 1 shows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) chart for this work.

Results

There were 11 relevant papers in this review, including six randomised controlled trials (RCTs) published between 2005 and 2018 with a total of 457 patients. In addition, there were five systematic reviews and meta-analysis on the subject, one of which is a network meta-analysis included in the discussion.
Primary data

There were six RCTs identified with primary data included in the review, as summarised in Table 1.

Secondary analysis

A total of five systematic reviews and meta-analysis were found to compare SH with RFH, as summarised in Table 2. These all included the relevant studies at the time of their publication; however, none included all six papers.

Intraoperative experience

Two of the studies reported on intraoperative outcomes. Basdanis et al. [2] recorded episodes of intraoperative bleeding, occurring in 36% of stapled procedures compared to 8.8% in the LigaSure (Medtronic, Minneapolis, MN, USA) group, \(P<0.05\). Kraemer et al. [8] also evaluated the ease of handling and immediate operative result as rated by the operating surgeon. There was no significant difference between the groups (\(P=0.5535\) for ease of use or \(P=0.4384\) for immediate results).

Five studies referred to operating times [2, 4, 7, 8, 14]; the findings were conflicting, with studies favouring different groups. The difference between approaches ranged from 2 to 7 min, and is therefore not clinically relevant.

Postoperative complications

Pain

Postoperative pain is a major problem associated with haemorrhoidectomy. Both SH and RFH have demonstrated lower pain scores compared to the conventional approach [15]. The RCTs mainly recorded analgesia use and pain scores on a visual analogue scale (VAS) at selected timepoints. The results are shown in Table 3.

There are three studies that found increased early postoperative pain in the RFH group [2, 4, 7] during the first week after surgery, although no significant difference was identified in the other three trials [1, 8, 14].

---

**Table 1** Summary of the baseline characteristics of the six randomised controlled trials directly comparing SH and RFH

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Country</th>
<th>Study type</th>
<th>Number of patients in study</th>
<th>Stapler</th>
<th>RF device</th>
<th>Grade of haemorrhoid included</th>
<th>Follow-up period</th>
<th>Sex M/F</th>
<th>Age Mean, years (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arslani et al. [1]</td>
<td>2012</td>
<td>Croatia</td>
<td>RCT</td>
<td>98</td>
<td>SH = 46</td>
<td>RFH = 52</td>
<td>PPH03</td>
<td>24 months</td>
<td>SH = 21/25</td>
<td>52 (17–72)</td>
</tr>
<tr>
<td>Basdanis et al. [2]</td>
<td>2005</td>
<td>Greece</td>
<td>RCT</td>
<td>95</td>
<td>SH = 50</td>
<td>RFH = 45</td>
<td>PPH01</td>
<td>18 months</td>
<td>SH = 29/21</td>
<td>46 (25–72)</td>
</tr>
<tr>
<td>Chen et al. [4]</td>
<td>2007</td>
<td>China</td>
<td>RCT</td>
<td>86</td>
<td>SH = 44</td>
<td>RFH = 42</td>
<td>Not stated</td>
<td>6 months</td>
<td>SH = 26/18</td>
<td>48 (25–81)</td>
</tr>
<tr>
<td>Ibrahim et al. [7]</td>
<td>2018</td>
<td>Egypt</td>
<td>RCT</td>
<td>60</td>
<td>SH = 30</td>
<td>RFH = 30</td>
<td>AVENTAL</td>
<td>Not stated</td>
<td>SH = 20/10</td>
<td>40 (20–60)</td>
</tr>
<tr>
<td>Kraemer et al. [8]</td>
<td>2005</td>
<td>Germany</td>
<td>RCT</td>
<td>50</td>
<td>SH = 25</td>
<td>RFH = 25</td>
<td>Ethicon</td>
<td>Grade 3 &amp; 4</td>
<td>SH = 14/11</td>
<td>58 (40–71)</td>
</tr>
<tr>
<td>Sakr et al. [14]</td>
<td>2010</td>
<td>Kuwait</td>
<td>RCT</td>
<td>68</td>
<td>SH = 34</td>
<td>RFH = 34</td>
<td>Ethicon</td>
<td>Grade 3 &amp; 4</td>
<td>SH = 21/13</td>
<td>44 (29–56)</td>
</tr>
</tbody>
</table>

PPH01 & PPH03 are Ethicon circular stapling devices (Ethicon, J&J Medical Devices, Somerville, NJ, USA); HEM3348 is a Covidien circular stapling device (Covidien; Medtronic, Minneapolis, MN, USA); AVENTAL is a circular haemorrhoidal stapling device (Avental Ltd. London, UK); LigaSure is a Medtronic product

**Table 2** Summary of the five systematic reviews and meta-analysis directly comparing SH and RFH

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Number of patients</th>
<th>Comparison</th>
<th>Relevant studies included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen et al. [4]</td>
<td>2014</td>
<td>397</td>
<td>LigaSure versus stapled</td>
<td>Arslani [1], Basdanis [2], Chen [4], Kraemer [8], Sakr [14]</td>
</tr>
<tr>
<td>Lee et al. [9]</td>
<td>2013</td>
<td>311</td>
<td>LigaSure versus stapled</td>
<td>Arslani [1], Basdanis [2], Kraemer [8], Sakr [14]</td>
</tr>
<tr>
<td>Similis et al. [15]</td>
<td>2015</td>
<td>397 direct comparisons, wider analysis 7827</td>
<td>Surgical treatments for haemorrhoids—Network meta-analysis</td>
<td>Arslani [1], Basdanis [2], Chen [4], Kraemer [8], Sakr [14] (98 trials in total)</td>
</tr>
<tr>
<td>Yang et al. [18]</td>
<td>2013</td>
<td>397</td>
<td>LigaSure versus stapled</td>
<td>Arslani [1], Basdanis [2], Chen [4], Kraemer [8], Sakr [14]</td>
</tr>
</tbody>
</table>

SH stapled haemorrhoidopexy; RFH radiofrequency haemorrhoidectomy; RCT randomised controlled trial, M male, F female
Abstract

Background. Multiple operations exist to treat haemorrhoids. Although comparisons of conventional excision and other techniques have been performed, there are less comparative outcome data available for stapled haemorrhoidopexy (SH) and radiofrequency haemorrhoidectomy (RFH). Use of a radiofrequency energy device for haemorrhoidectomy is an alternative to standard diathermy, scissors or scalpel. It provides vessel sealing between the jaws of the instrument and aims to minimise wider tissue damage.

Objective. To systematically review the literature comparing SH and RFH, assessing complications, outcomes, patient experience and costs.

Methods. A tailored search of medical databases identified literature containing relevant primary and secondary data comparing SH and RFH. Papers were screened for relevance and completeness of published data. Those missing methodological information, outcome data or statistical analysis were subsequently excluded. A narrative review was then performed.

Results. The primary data in this review originate from six randomised control trials (RCTs) and five meta-analyses. Evidence was conflicting, with a trend towards more early postoperative pain in the RFH vs. the SH group (three RCTs reported increased early pain scores in the RFH group). Significantly higher rates of residual and recurrent haemorrhoids and prolapse in the SH group were observed in two RCTs and four meta-analyses. Bleeding, urinary retention, incontinence and anal stenosis did not significantly differ. No detailed contemporary cost analysis was found.

Conclusion. The trials are small, with significant heterogeneity in the techniques used and outcome data recorded. However, despite the limited available evidence, RFH appears superior to SH due to significantly lower rates of residual and recurrent haemorrhoids and prolapse.

Keywords
Haemorrhoids · Pain · Cost · Postoperative complications · Prolapse

Wer braucht einen Stapler zur Hämorrhoidektomie, wenn es das Hochfrequenzgerät gibt?

Zusammenfassung


Schlüsselwörter
Hämorrhoiden · Schmerz · Kosten · Postoperative Komplikationen · Prolapse

The data collected are heterogenous, with variations in technique and endpoints.

In contrast to the other studies, during SH, Kraemer et al. [8] excised the external haemorrhoids with scissors. During haemorrhoidectomy with the radiofrequency device, Sakr et al. [14] used the conventional Milligan and Morgan technique with scissors below the dentate line and only applied the LigaSure device above the dentate line. However, three meta-analyses attempted to pool the data [3, 9, 18], and all found no significant difference in postoperative pain between the two procedures.

The network meta-analysis by Simillis et al. [15] found significantly more postoperative pain following LigaSure haemorrhoidectomy compared to SH at day 14.

Bleeding, urinary retention and incontinence

Common early postoperative complications include bleeding, urinary retention and incontinence in particular; these are summarised in Table 4.

There were no consistent differences between the approaches identified across the studies. The only significant finding was an increase in bleeding in the SH
Table 3  Summary of analgesia use and pain scores reported in the six RCTs

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of patients</th>
<th>Analgesia use</th>
<th>Pain Visual analogue scale (range 0–10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arslani et al. [1]</td>
<td>SH = 46</td>
<td>Dose needed over first 5 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RFH = 52</td>
<td>– No analgesia – Tramadol 200mg – Tramadol &gt;200mg – Pethidine 100mg</td>
<td>Median score (range) over first 5 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difference between groups</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$P = 0.862$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$P = 0.837$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$P = 0.902$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$P = 0.941$</td>
<td></td>
</tr>
<tr>
<td>Basdanis et al. [2]</td>
<td>SH = 50</td>
<td>– Not reported</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RFH = 45</td>
<td>Difference between groups</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$P = 0.862$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$P = 0.837$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$P = 0.902$</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$P = 0.941$</td>
<td></td>
</tr>
<tr>
<td>Chen et al. [4]</td>
<td>SH = 44</td>
<td>Incomplete data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RFH = 42</td>
<td>Median (range)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 (1–6) at 24h</td>
<td></td>
</tr>
<tr>
<td>Ibrahim et al. [7]</td>
<td>SH = 30</td>
<td>Mean dose of narcotic analgesia Day 1–3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RFH = 30</td>
<td>Mean dose of diclofenac on Day 4 and 7 Day 14</td>
<td></td>
</tr>
<tr>
<td>Kraemer et al. [8]</td>
<td>SH = 25</td>
<td>Analgesic requirements over first 21 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RFH = 25</td>
<td>Difference between groups</td>
<td></td>
</tr>
<tr>
<td>Sakr et al. [14]</td>
<td>SH = 34</td>
<td>Mean number of injections (SD) 5.76 (± 0.855)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RFH = 34</td>
<td>Parenteral analgesic injections $P = 0.518$</td>
<td></td>
</tr>
</tbody>
</table>

**Italicics = significant difference in favour of SH; bold = significant difference in favour of RFH; no highlight = no significant difference**

SH stapled haemorrhoidopexy, RFH radiofrequency haemorrhoidectomy, RCT randomised controlled trial, SD standard deviation

Anal stenosis and recurrence

Long-term complications include anal stenosis and recurrence of both haemorrhoids and prolapse; these findings are summarised in Table 5.

In two studies [2, 7] there were significantly higher rates of haemorrhoid recurrence and prolapse in the SH group. The meta-analyses by Chen [3] (odds ratio, OR, 0.18 for recurrence in RFH, $P = 0.01$), Lee [9] (OR 5.53 for recurrence in SH, $P = 0.016$) and Yang et al. [18] (OR 0.21 for recurrence in RFH, $P = 0.003$), and the network analysis by Simillis et al. [15] also found significantly higher recurrence rates in the SH compared to the RFH group. Residual prolapse and skin tags were recorded by two studies [1, 14], both of which found a significantly higher incidence in the SH group ($P = 0.04$ and $P = 0.024$, respectively).

Life-threatening complications are rare after haemorrhoid surgery. Most case reports are associated with SH [13]. Rectal perforation, rectovaginal fistulae and sepsis have been reported, and there is an estimated 10% risk of mortality if the sepsis is secondary to SH [5]. None of these complications were identified in the presented studies.

Patient experience

Three studies referred to length of hospital stay [2, 7, 14]. There was no significant difference between the two groups, with results ranging from 20h to 2.44 days. Four studies [1, 2, 7, 14] provided time to return to work or normal activities. The range of values lay between 6 days...
and 3 weeks, but none of these studies demonstrated a significant difference between the techniques.

Kraemer [8] and Chen et al. [4] both refer to patient satisfaction, with seemingly high self-reported scores and no significant differences between groups.

### Costs

In 2004, Basdanis et al. [2] reports a surgical cost of 1175 Euros for SH and 780 Euros for RFH using the LigaSure device. With the addition of length of stay and medications, the costs were 1504 and 1268 Euros, respectively. Chen et al. [4] estimated the average costs for SH to be 748 Euros and for LigaSure to be 464 Euros ($P < 0.05$) in 2007 (converted from Yuan based on 1 Yuan to 0.096 Euros). These are not contemporary prices; the range of products available has expanded and although the evidence presented is limited to the LigaSure device, cheaper devices and staplers are available. In view of this, without an up-to-date cost analysis, it is difficult to draw any conclusions.

### Discussion

In this review, SH was associated with significantly higher rates of residual and recurrent haemorrhoids during follow-up compared to RFH, although RFH appeared to show higher early pain scores compared to the stapled group. The eTHoStrial [17] established the superiority of conventional haemorrhoidectomy over SH, illustrating a similar picture of lower recurrence rates for the conventional technique, albeit with higher pain scores.

There were no significant differences in terms of hospital stay, return to work or normal activities and patient satisfaction, although no detailed quality of life data were recorded by any of the studies. Two studies compared costs; however, both are over 10 years old, and it is therefore
unclear which procedure would be considered most cost-effective nowadays.

There are a number of limitations of the six RTCs included, particularly the small size, significant variation in techniques and heterogeneity of the outcomes measured. The only radiofrequency device used was the LigaSure.

**Conclusion**

Despite the limited evidence currently available, radiofrequency haemorrhoidectomy appears to be superior to stapled haemorrhoidopexy.

**Corresponding address**

Prof. A. J. M. Watson
Colorectal Surgery, Raigmore Hospital
Old Perth Rd, IV2 3UJ Inverness, Scotland, UK
angus.watson@nhs.net

**Compliance with ethical guidelines**

**Conflict of interest** A. Sunny, H. Sellars, G. Ramsay, R. Polson and A. J. M. Watson declare that they have no competing interests.

For this article no studies with human participants or animals were performed by any of the authors. All studies performed were in accordance with the ethical standards indicated in each case.

**Open Access** This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made.

**References**