

# A Systematic Review of Stapled Hemorrhoidectomy

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**Hypothesis:** Use of circular stapled hemorrhoidectomy will result in the same or improved safety and efficacy outcomes as those of the conventional methods for hemorrhoidectomy in patients with hemorrhoids.

**Data Sources:** Studies on stapled hemorrhoidectomy were identified using PREMEDLINE and MEDLINE (June 1966–June 2001), EMBASE (January 1980–June 2001), Current Contents (June 1993–June 2001), Ovid HEALTHSTAR (January 1975–June 2001), the National Institutes of Health Clinical Trials database (searched June 13, 2001), and The National Coordinating Centre for Health Technology Assessment database (searched June 14, 2001). The search terms were as follows: *haemorrhoid\** and (*stapl\** or *convent\**) or *hemorrhoid\** and (*stapl\** or *convent\**). The Cochrane Library (2001, issue 2) was searched using the search terms *haemorrhoid\** or *hemorrhoid\**.

**Study Selection:** Articles detailing randomized controlled trials were included if they compared circular stapled with conventional hemorrhoidectomy and provided relevant safety and efficacy outcome information.

**Data Extraction:** Data from all included studies were extracted using standardized data extraction tables that were developed a priori. In addition, the randomized controlled trials were examined with respect to the adequacy of allocation concealment, handling of those un-

available for follow-up, and any other aspect of the study design or execution that may have introduced bias.

**Data Synthesis:** Seven randomized controlled trials met the inclusion criteria. A meta-analysis was conducted when the studies had comparable outcomes, inclusion criteria, and follow-up. There was reasonably clear evidence in favor of the stapled procedure for bleeding at 2 weeks (relative risk, 0.55; 95% confidence interval, 0.37-0.82) and length of hospital stay (weighted mean difference, -0.89 days; 95% confidence interval, -1.42 to -0.36). Other less robust results in favor of the stapled hemorrhoidectomy related to pain, bleeding, anal discharge, wound healing, tenderness to per rectal examination, incontinence scores, earlier return of bowel function, analgesic requirement, and resumption of normal activities. One trial showed that prolapse occurred at significantly higher rates in the stapled hemorrhoidectomy group. However, the outcomes were poorly reported and generally showed statistically significant heterogeneity.

**Conclusions:** Stapled hemorrhoidectomy may be at least as safe as conventional hemorrhoidal surgical techniques. However, the efficacy of the stapled procedure compared with the conventional techniques could not be determined. More rigorous studies with longer follow-up periods and larger sample sizes need to be conducted.

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**I**NTERNAL HEMORRHOIDS develop when cushions of vascular tissue in the anus undergo pathological change. These cushions have an important role in maintaining continence because they function, along with the internal anal sphincter, to allow the complete closure of the anal canal.<sup>1</sup> Hemorrhoids can be thought of as symptomatic aggregations of this subepithelial tissue<sup>2</sup> that may cause bleeding, mucosal or fecal soiling, itching, and occasional pain.<sup>1</sup> The prevalence of hemorrhoids is estimated at between 4% and 34%.<sup>3</sup>

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Numerous theories concerning the pathogenesis of hemorrhoids have been proposed, but the exact mechanism remains

## See Invited Critique at end of article

elusive. It has been suggested that they may arise as a result of increased intra-abdominal pressure, portal hypertension, constipation and straining during discharge of feces, connective tissue abnormalities, or tissue metaplasia.<sup>3</sup> Hemorrhoids vary in their severity and tendency to prolapse, and are

**Table 1. Designations of Levels of Evidence\***

| Level of Evidence | Study Design  |
|-------------------|---|
| I                 | Evidence obtained from a systematic review of all relevant randomized controlled trials   |
| II                | Evidence obtained from at least 1 properly designed randomized controlled trial   |
| III               |   |
| 1                 | Evidence obtained from well-designed pseudorandomized controlled trials (alternate allocation or some other method)   |
| 2                 | Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomized, cohort studies, case-control studies, or interrupted time series with a control group |
| 3                 | Evidence obtained from comparative studies with historical control, 2 or more single-arm studies, or interrupted time series without a parallel control group   |
| IV                | Evidence obtained from case series, either posttest or pretest/posttest   |

\*Data from the National Health and Medical Research Council.<sup>16</sup>

graded accordingly. At grades 1 and 2, they are treated conservatively by rubber band ligation and/or injection sclerotherapy. At grades 3 and 4, hemorrhoids that persistently prolapse may require surgical intervention. Unfortunately, surgical hemorrhoidectomy is often accompanied by a high incidence of complications, including urinary retention, hemorrhage, constipation and fecal impaction, and significant postoperative pain.<sup>4</sup>

Attention has, therefore, focused on less painful methods for the surgical treatment of hemorrhoids. Modifications to conventional techniques include the addition of lateral internal sphincterotomy, closed hemorrhoidectomy, anal dilatation, and anal sphincter relaxants. However, these techniques have not significantly reduced postoperative pain.<sup>5</sup>

Most recently, circular stapled rectal hemorrhoidectomy, sometimes known as circular stapled rectal mucosectomy, has emerged as a potentially less painful alternative. The operation reduces the size of internal hemorrhoids by interrupting their blood supply, therefore reducing the size of the vascular cushions and reducing the available rectal mucosa for the potential of prolapse. Whereas conventional surgical hemorrhoidectomy involves excision of hemorrhoidal tissue, anoderm, and perianal skin, stapled hemorrhoidectomy simply excises an annulus of rectal mucosa above the pathological rectal mucosa (hemorrhoids).

After dilatation of the anal canal, a purse-string suture is placed 4 cm above the dentate line.<sup>6</sup> Subsequently, a circular stapler is introduced transanally. The anvil of the device is positioned proximal to the purse-string suture, and the suture is tied down onto the anvil. Retraction of the suture pulls the attached rectal mucosa into the stapler. Closure of the anvil and firing of the stapler simultaneously excises a ring of mucosa proximal to the hemorrhoid(s), thus interrupting the blood supply<sup>7</sup> but maintaining continuity of the rectal mucosa.<sup>8</sup>

Recent evidence<sup>6,7,9-15</sup> has suggested that this technique is accompanied by good postoperative outcomes. Nevertheless, the long-term sequelae of the operation are

unknown. Therefore, this review compares the safety and efficacy outcomes of stapled hemorrhoidectomy with those of conventional surgical techniques.

## METHODS

This review is a summary of information obtained during the assessment of the stapled hemorrhoidectomy technique for the Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S). The aims of ASERNIP-S are to assess the safety and efficacy of new surgical procedures and to determine whether they are appropriate for widespread use or require further evaluation.

### THE ASERNIP-S REVIEW PROCESS

A surgeon (J.L.S.) familiar with the topic of review (protocol surgeon) and an ASERNIP-S researcher (L.M.S.) drafted the protocol for the systematic literature review and selected the studies to be included, according to the predetermined selection criteria. Two reviewers (L.M.S. and A.K.B.) performed independent data extraction. A review group, comprising the advisory (E.L.B.) and protocol (J.L.S.) surgeons, a nominated surgeon (P.A.C.) from the Colon and Rectal Surgery Section of the Royal Australasian College of Surgeons, a surgeon (A.K.R.) from another specialty, and an ASERNIP-S researcher (L.M.S.), considered the systematic literature review, determined a classification (**Table 1**), and made clinical and research recommendations. Once consensus was reached, the review, with its classifications and recommendations, was presented to the ASERNIP-S Management Committee and, subsequently, to the Council of the Royal Australasian College of Surgeons for endorsement.

### SEARCH STRATEGY

All original, published, human studies on stapled hemorrhoidectomy were identified by searching PREMEDLINE and MEDLINE between June 1966 and June 2001, Current Contents between June 1993 and June 2001, EMBASE between January 1980 and June 2001, Ovid HEALTHSTAR between January 1975 and June 2001, the National Institutes of Health Clinical Trials database on June 13, 2001, and The National Coordinating Centre for Health Technology Assessment database on June 14, 2001. The search terms used were as follows: *haemorrhoid\** and (*stapl\** or *convent\**) or *hemorrhoid\** and (*stapl\** or *convent\**), with no language or date restrictions applied. The Cochrane Library (2001, issue 2) was searched using the terms *haemorrhoid\** or *hemorrhoid\**. (The truncation symbol, \*, differs in each database and allows retrieval of all possible suffix variations of a root word.)

Additional articles were identified by checking the reference sections of all studies retrieved from the searches. Foreign-language articles were not translated unless, based on their abstracts, they offered significantly different or more extensive results than those reported in the English-language articles. Because this did not occur, only English-language articles were included for review.

### INCLUSION CRITERIA

Only randomized controlled trials (RCTs) comparing conventional hemorrhoidectomy (excision-ligation, closed hemorrhoidectomy, or diathermy, which may or may not be ligated) with circular stapled hemorrhoidectomy were included. Comparative studies (historical and nonrandomized), case series, and case reports were not included. Only full peer-reviewed articles were included.

**Table 2. Summary of the Included Studies**

| Source*                                | Total No. of Patients<br>(Conventional/Stapled<br>Hemorrhoidectomy Group) | Conventional Technique             | Stapler Type Used†                        |
|--|---|------------------------------------|---|
| Boccasanta et al, <sup>13</sup> 2001   | 80 (40/40)  | Modified Milligan-Morgan           | Circular stapler                          |
| Brown et al, <sup>12</sup> 2001        | 30 (15/15)  | Open diathermy and Milligan-Morgan | Circular stapler (standard PPH equipment) |
| Ganio et al, <sup>11</sup> 2001        | 100 (50/50)   | Open diathermy                     | Circular stapler                          |
| Ho et al, <sup>14</sup> 2000           | 119 (62/57)   | Open diathermy                     | Circular stapler (standard PPH equipment) |
| Mehigan et al, <sup>7</sup> 2001       | 40 (20/20)  | Open diathermy and Milligan-Morgan | Circular stapler                          |
| Rowell et al, <sup>15</sup> 2001       | 22 (11/11)  | Diathermy                          | Circular stapler (standard PPH equipment) |
| Shalaby and Desoky, <sup>10</sup> 2001 | 200 (100/100)   | Milligan-Morgan                    | "Proximate" circular stapler              |

\*All studies are level II evidence. Levels of evidence are explained in Table 1. PPH indicates procedure for prolapsed hemorrhoids.

†All staplers were marketed by Ethicon Endosurgery, a division of Johnson & Johnson in Cincinnati, Ohio.

**Table 3. Pooled Summary of RR of Postoperative Safety Outcomes After Stapled Compared With Conventional Hemorrhoidectomy\***

| Outcome                                    | References    | RR (95% CI)                                  | P Value (Test of Statistical Heterogeneity) |
|--|---------------|--|---|
| Bleeding                                   |               |  |   |
| 2 wk                                       | 13 and 14     | 0.55 (0.37-0.82)                             | .21   |
| 6 wk                                       | 12 and 14     | RE: 0.55 (0.05-6.71)<br>FE: 0.88 (0.38-1.97) | .08   |
| 2-3 mo                                     | 10 and 14     | 0.52 (0.10-2.80)                             | .65   |
| Hemorrhage requiring sutures               | 7 and 11      | 1.33 (0.50-3.57)                             | .62   |
| Secondary hemorrhage requiring transfusion | 7, 13, and 14 | 0.24 (0.41-1.40)                             | .92   |
| Thrombosis of the external hemorrhoids     | 10 and 13     | 0.56 (0.19-1.61)                             | .75   |
| Urinary retention                          | 7, 10, and 13 | 0.59 (0.28-1.24)                             | .96   |
| Anal stenosis                              |               |  |   |
| 2-6 wk                                     | 12 and 14     | 1.07 (0.36-3.17)                             | .57   |
| Long-term                                  | 10 and 13     | 0.45 (0.14-1.46)                             | .33   |
| Internal sphincter damage                  | 12 and 14     | 0.70 (0.21-2.37)                             | .63   |

\*All outcomes were combined under the fixed-effects (FE) model, except bleeding at 6 weeks, which was also combined using a random-effects (RE) model. RR indicates relative risk.

Studies of patients with all levels of hemorrhoids were considered. Studies in which patients with any additional surgical diseases that were treated at the same time as hemorrhoidectomy were excluded unless separate data for these patients were available. The protocol surgeon and the ASERNIP-S researcher assessed the articles based on the inclusion criteria, and a consensus was reached about their inclusion.

## OBJECTIVES AND COMPARISONS

For this review, the question of safety was addressed in terms of whether stapled hemorrhoidectomy was more or less likely to cause harm or injury to the patient compared with conventional hemorrhoidectomy. Therefore, a range of major and minor postoperative complications was assessed, such as bleeding and stenosis. For efficacy, the question was whether stapled hemorrhoidectomy produced at least equivalent clinical outcomes compared with conventional hemorrhoidectomy. Efficacy end points, such as postoperative measurements of pain, analgesic requirement, wound and anal discharge, wound healing time, prolapse, reduction of residual acrochordons (skin tags), anal resting and squeeze volumes, and readmission rate, were assessed.

## DATA AND STATISTICAL ANALYSES

A meta-analysis was conducted on the RCTs if the studies had comparable outcomes, inclusion criteria, and follow-up. The level II evidence was limited by the small sample size and short follow-up period.

The heterogeneity between trials was analyzed with  $\chi^2$  tests. Because statistical tests of heterogeneity lack power,<sup>17,18</sup>  $P < .10$  was

used to indicate significant heterogeneity. When there was no significant statistical heterogeneity, a fixed-effects model was used to calculate summary relative risks (RRs), weighted or standardized mean differences, and the 95% confidence intervals; otherwise, a random-effects model was also calculated. The stapled procedure was considered better than the conventional method when the upper limit of the 95% confidence interval of the RR was less than 1 for dichotomous outcomes and greater than 0 for continuous outcomes. All statistical values were calculated with statistical software (RevMan 4.1; Update Software Ltd, Oxford, United Kingdom).

## RESULTS

Of the 7 RCTs (level II evidence) that met the inclusion criteria, only one<sup>11</sup> was conducted as a multicenter trial (**Table 2**). All included studies had blinded patients to the outcomes, and in 4 of the studies,<sup>7,12-14</sup> outcome assessors were also blinded. Randomization was conducted by either sealed envelopes<sup>7,11-15</sup> or a table of random numbers<sup>10</sup>; however, an adequate method of allocation concealment (centrally randomized) was stated only in one study.<sup>11</sup> Follow-up times varied between the studies, with the longest being 1 year.<sup>10,13</sup>

## SAFETY

A meta-analysis of the safety data is presented in **Table 3**, and the full results of the individual studies are shown in **Table 4**. Statistical heterogeneity between the RCTs

**Table 4. Summary of Safety Results\***

| Safety Outcomes   | Boccasanta et al <sup>13</sup> |                | Brown et al <sup>12</sup> |                | Ganio et al <sup>11</sup> |                | Ho et al <sup>14</sup> |                | Mehigan et al <sup>7</sup> |                | Rowell et al <sup>15</sup> |                | Shalaby and Desoky <sup>10</sup> |                 |
|---|--------------------------------|----------------|---------------------------|----------------|---------------------------|----------------|------------------------|----------------|----------------------------|----------------|----------------------------|----------------|----------------------------------|-----------------|
|   | CNV<br>(n = 40)                | St<br>(n = 40) | CNV<br>(n = 15)           | St<br>(n = 15) | CNV<br>(n = 50)           | St<br>(n = 50) | CNV<br>(n = 62)        | St<br>(n = 57) | CNV<br>(n = 20)            | St<br>(n = 20) | CNV<br>(n = 11)            | St<br>(n = 11) | CNV<br>(n = 100)                 | St<br>(n = 100) |
| Bleeding  |                                |                |                           |                |                           |                |                        |                |                            |                |                            |                |                                  |                 |
| In the hospital   | ...                            | ...            | ...                       | ...            | ...                       | ...            | 1.6                    | 3.5            | ...                        | ...            | ...                        | ...            | ...                              | ...             |
| Postoperatively   |                                |                |                           |                |                           |                |                        |                |                            |                |                            |                |                                  |                 |
| 2 wk  | ...                            | ...            | 67                        | 20†            | ...                       | ...            | 53.3                   | 33.3†          | ...                        | ...            | ...                        | ...            | ...                              | ...             |
| 6 wk  | ...                            | ...            | 27                        | 0†             | ...                       | ...            | 11.3                   | 15.8           | ...                        | ...            | ...                        | ...            | ...                              | ...             |
| 2-3 mo  | ...                            | ...            | ...                       | ...            | ...                       | ...            | 3.2                    | 1.8            | ...                        | ...            | ...                        | ...            | 2                                | 1               |
| Long-term (8-19 mo)   | ...                            | ...            | ...                       | ...            | 32                        | 28‡            | ...                    | ...            | ...                        | ...            | ...                        | ...            | ...                              | ...             |
| Bleeding requiring medical consultation, intervention, or rehospitalization at 2 wk postoperatively | ...                            | ...            | 13                        | ...            | ...                       | ...            | 16.1                   | 5.3            | 5                          | ...            | ...                        | ...            | ...                              | ...             |
| Hemorrhage  |                                |                |                           |                |                           |                |                        |                |                            |                |                            |                |                                  |                 |
| Requirement for hemostatic sutures  | ...                            | 12.5           | ...                       | ...            | 6                         | 6              | ...                    | ...            | 15                         | 25             | ...                        | ...            | ...                              | ...             |
| Requirement for transfixed suture   | 5                              | ...            | ...                       | ...            | ...                       | ...            | ...                    | ...            | ...                        | ...            | ...                        | ...            | ...                              | ...             |
| 2° Hemorrhage requiring transfusion   | 2.5                            | 0              | ...                       | ...            | ...                       | ...            | 4.8                    | 0              | 5                          | 0              | ...                        | ...            | ...                              | ...             |
| Thrombosis of external piles  | 15                             | 5§             | ...                       | ...            | ...                       | ...            | 1.8                    | ...            | ...                        | ...            | ...                        | ...            | 3                                | 3               |
| Urinary retention   | 5                              | 5‡             | ...                       | ...            | ...                       | ...            | 1.8                    | ...            | 5                          | 5              | ...                        | ...            | 14                               | 7               |
| Anal stenosis and stricture postoperatively   |                                |                |                           |                |                           |                |                        |                |                            |                |                            |                |                                  |                 |
| 2-6 wk  | ...                            | ...            | 7                         | 7‡             | ...                       | ...            | 8.1                    | 8.8            | ...                        | ...            | ...                        | ...            | ...                              | ...             |
| ≤1 y  | 7.5                            | 5‡             | ...                       | ...            | ...                       | ...            | ...                    | ...            | ...                        | ...            | ...                        | ...            | 6                                | 2               |
| Anal fissure  | ...                            | ...            | ...                       | ...            | ...                       | ...            | ...                    | ...            | 5                          | 5              | ...                        | ...            | 3                                | 1               |
| Internal sphincter damage (6 wk-3 mo postoperatively)   | ...                            | ...            | 13                        | 13             | ...                       | ...            | 6.5                    | 3.5            | ...                        | ...            | ...                        | ...            | ...                              | ...             |
| Total complications   | ...                            | ...            | ...                       | ...            | ...                       | ...            | 25.8                   | 17.5           | ...                        | ...            | ...                        | ...            | ...                              | ...             |

\*Data are given as percentage of patients. CNV indicates conventional hemorrhoidectomy group; St, stapled hemorrhoidectomy group; and ellipses, data not available.

†*P* < .05 compared with CNV.

‡Not statistically significant compared with CNV.

§*P* < .03 compared with CNV.

was only evident in the pooled safety outcome for bleeding at 6 weeks. Under these conditions, the RR was also calculated using the random model. The heterogeneity may have been because of differing postoperative care regimens that affected wound healing rates.

### Bleeding

In one trial,<sup>14</sup> bleeding during hospitalization was comparable in both treatment groups, although patient numbers in this study were small. Two patients in the stapled hemorrhoidectomy group (n=57) and one in the conventional treatment group (n=62) displayed bleeding that prolonged hospital stay for more than 1 day.

At 2 weeks, stapled hemorrhoidectomy conferred a 45% (95% confidence interval, 18%-63% [based on 2 RCTs<sup>12,14</sup>]) reduction in the risk of bleeding compared with the conventional technique. However, bleeding at 6 weeks postoperatively was inconclusive for the comparison between stapled and conventional treatments (under either a fixed- or a random-effects model). The statistical heterogeneity may be because of the effect of one large study or differences in the definition and/or reporting of postoperative bleeding between the 2 studies.<sup>12,14</sup>

Bleeding at 2 to 3 months was low in both treatment groups, and the pooled RRs were similarly inconclusive.<sup>10,14</sup> At long-term postoperative follow-up (range, 8-19 months), bleeding was lower in the stapled treatment group; the number of patients reporting episodes of bleeding was high in both groups.<sup>11</sup>

### Hemorrhage

There was an intraoperative requirement for hemostatic sutures for hemorrhage<sup>7,11</sup> for some patients in both groups. The pooled RRs were inconclusive, but suggested a trend toward a higher requirement for intervention with the stapled procedure. There was a trend toward reduced risk of secondary hemorrhage requiring blood transfusion following stapled hemorrhoidectomy.<sup>7,13,14</sup>

### Thrombosis

The incidence of thrombosis of the external hemorrhoidal plexus varied between the studies.<sup>10,13,14</sup> The pooled data for 2 studies<sup>10,13</sup> were inconclusive, but did suggest a trend toward a lower incidence with stapled hemorrhoidectomy.

**Table 5. Pooled Effect Measures of Postoperative Efficacy Outcomes After Stapled Compared With Conventional Hemorrhoidectomy\***

| Outcome                                 | References        | Effect Measure (95% CI)           | P Value<br>(Test of Statistical Heterogeneity) |
|---|-------------------|-----------------------------------|--|
| Operating time, min                     | 10, 13-15         | WMD: -7.64 (-19.12 to 3.84) (RE)  | <.001  |
| Length of hospital stay, d              | 10, 13-15         | WMD: -0.89 (-1.42 to -0.36) (RE)  | <.001  |
| Resumption of normal activities, d      | 10, 13-15         | SMD: -4.52 (-8.93 to -0.11) (RE)  | <.001  |
|   |                   | WMD: -16.87 (-42.49 to 8.74) (RE) | <.001  |
| Readmission                             | 12 and 14         | RR: 0.15 (0.02 to 1.17) (FE)      | .97  |
| Pain during hospitalization (VAS score) | 10 and 14         | WMD: -2.83 (-7.34 to 1.68) (RE)   | <.001  |
| Wound discharge at 2 wk                 | 12 and 14         | RR: 0.57 (0.27 to 1.19) (FE)      | .59  |
| Acrochordons at 2-3 mo                  | 7, 10, 13, and 14 | RR: 3.06 (0.85 to 11.04) (FE)     | .72  |

\*CI indicates confidence interval; WMD, weighted mean difference; RE, random-effects model; SMD, standardized mean difference; RR, relative risk; FE, fixed-effects model; and VAS, visual analog scale.

### Urinary Retention

For postoperative urinary retention, the pooled RR across 3 of the studies<sup>7,10,13</sup> was inconclusive. However, there was a trend for fewer patients in the stapled hemorrhoidectomy group presenting with urinary retention, influenced by the results of one large study.<sup>10</sup>

### Anal Stricture, Stenosis, and Fissure

There was no detectable difference between the stapled and conventional treatment in the incidence of anal stricture and stenosis during the early postoperative period<sup>12,14</sup> and at up to 1 year of follow-up.<sup>10,13</sup> However, there was a suggestion of a lower long-term incidence in the stapled hemorrhoidectomy group. There was a low incidence of anal fissure in the stapled and the conventional hemorrhoidectomy groups.

### Sphincter Damage

Studies that measured this outcome did so by endoanal ultrasonography. The pooled RRs of internal sphincter damage were inconclusive, with one study<sup>12</sup> not finding a treatment-dependent difference in internal sphincter damage but another study<sup>14</sup> finding that it occurred less frequently in the stapled hemorrhoidectomy group. (Internal sphincter damage was present in one patient from each treatment group before surgery in the latter study.)

### Total Number of Complications

The total number of complications was assessed in one study.<sup>14</sup> Patients in the conventional hemorrhoidectomy group had higher complication rates than patients in the stapled hemorrhoidectomy group. This difference was not statistically significant, and an analysis of the nature, seriousness, and severity of the complications for each patient group was not reported.

### EFFICACY

Pooled efficacy data are presented in **Table 5**, and the full results of the individual studies are shown in **Table 6**. Statistical heterogeneity between the studies was evident for the outcomes of operating time, length of hos-

pital stay, resumption of usual activities, and in-hospital visual analog scale pain score.

### Operating Time

The mean operating time was reported and able to be pooled in 4 studies.<sup>10,13-15</sup> There was no discernible difference in operation time between the 2 procedures in these studies. The statistical heterogeneity between the studies may have resulted from variations in the method used to measure the time to perform surgery and in the time when surgery was deemed to have started. There may also have been inconsistencies across the studies in defining when the operation started. A median time of 15 minutes was reported for both of the treatment methods in the unpooled study.<sup>12</sup>

### Length of Hospital Stay

Pooling of 4 studies<sup>10,13-15</sup> resulted in an overall reduction of nearly 1 day, although statistical heterogeneity was present.

Three other studies<sup>7,11,12</sup> reported the median for the length of hospital stay for the conventional and the stapled treatment groups (1-2 days for both). The mean and SD was reported for the 4 other studies.<sup>10,13-15</sup> The heterogeneity across the 4 pooled studies<sup>10,13-15</sup> may be a reflection of differences in hospital discharge protocols and the way in which the length of hospital stay was determined in these studies.

### Resumption of Normal Activities

The resumption of normal activities was on average quicker in the stapled hemorrhoidectomy groups compared with the conventional hemorrhoidectomy groups,<sup>10,13-15</sup> although there was statistical heterogeneity between the studies. The pooled data across the 4 studies was statistically significant when the effects were calculated as a standardized mean difference. However, when the data were combined by weighted mean difference, the estimate of effect was not statistically significant. These variations in effects may possibly be due to variations in patient interpretation and assessment of the outcome and, thus, the result was inconclusive. This was consistent with other studies<sup>7,11,12</sup> that reported a median of 5 to 17 days for the

**Table 6. Summary of Efficacy Results<sup>a</sup>**

| Efficacy Outcomes  | Boccasanta et al <sup>13</sup> |                        | Brown et al <sup>12</sup> |                          | Ganio et al <sup>11</sup>       |                                 |
|--|--------------------------------|------------------------|---------------------------|--------------------------|---------------------------------|---------------------------------|
|  | CNV<br>(n = 40)                | St<br>(n = 40)         | CNV<br>(n = 15)           | St<br>(n = 15)           | CNV<br>(n = 50)                 | St<br>(n = 50)                  |
| <b>Perioperatively</b>   |                                |                        |                           |                          |                                 |                                 |
| Operating time, min  | 50 (5.3)                       | 25 (3.1) <sup>b</sup>  | 15 (5-25) <sup>c</sup>    | 15 (10-40) <sup>cd</sup> | ...                             | ...                             |
| Length of hospital stay, d   | 3 (0.4)                        | 2 (0.5) <sup>e</sup>   | 2 (2-4) <sup>c</sup>      | 2 (1-5) <sup>df</sup>    | 2 (0-12) <sup>c</sup>           | 1 (0-3) <sup>de</sup>           |
| Resumption of usual activities (including employment), d                           | 15 (1.4)                       | 8.0 (0.9) <sup>b</sup> | 28 (14-81) <sup>c</sup>   | 14 (5-43) <sup>cd</sup>  | 13 (3-25) (n = 37) <sup>c</sup> | 5 (1-16) (n = 35) <sup>cd</sup> |
| <b>Readmission<sup>l</sup></b>   |                                |                        |                           |                          |                                 |                                 |
|  | ...                            | ...                    | 20                        | 0 <sup>f</sup>           | ...                             | ...                             |
| <b>Pain</b>  |                                |                        |                           |                          |                                 |                                 |
| During hospitalization (VAS score)   | ...                            | ...                    | 1 (0-10) <sup>c</sup>     | 5 (2-10) <sup>c</sup>    | ...                             | ...                             |
| 1 wk postsurgery   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| Average over 10 d postsurgery (VAS score)  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| 2 wk postsurgery (VAS score)   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| 6 wk postsurgery <sup>j</sup>  | ...                            | ...                    | 33                        | 0 <sup>f</sup>           | ...                             | ...                             |
| Relative to what was expected (VAS score)  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Persistent pain</b>   |                                |                        |                           |                          |                                 |                                 |
| 3 mo postsurgery <sup>j</sup>  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| Long-term (range, 8-19 mo) <sup>j</sup>  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| Occasionally   | ...                            | ...                    | ...                       | ...                      | 28                              | 18                              |
| Frequently   | ...                            | ...                    | ...                       | ...                      | 2                               | 2                               |
| <b>Pain during discharge of feces</b>  |                                |                        |                           |                          |                                 |                                 |
| During hospitalization (VAS score)   | ...                            | ...                    | 3 (0-7) <sup>c</sup>      | 6 (1-10) <sup>cd</sup>   | ...                             | ...                             |
| 2 wk postsurgery (VAS score)   | ...                            | ...                    | 6 (1-10) <sup>c</sup>     | 0 (0-7) <sup>dk</sup>    | ...                             | ...                             |
| <b>Bowel movement before discharge<sup>l</sup></b>                                 |                                |                        |                           |                          |                                 |                                 |
|  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Resumed bowel function within 24 h<sup>l</sup></b>                              |                                |                        |                           |                          |                                 |                                 |
|  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Analgesic requirement</b>   |                                |                        |                           |                          |                                 |                                 |
| No. of doses/d   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| Required analgesia <sup>l</sup>  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| Composite pain score (No. of analgesics/No. of days of consumption)                | ...                            | ...                    | ...                       | ...                      | 1.5 (0.5)                       | 1.4 (0.5) <sup>l</sup>          |
| <b>IM meperidine hydrochloride (1 mg/kg of body weight)</b>                        |                                |                        |                           |                          |                                 |                                 |
| <b>Ketoprofen (100-mg tablet)</b>  |                                |                        |                           |                          |                                 |                                 |
| <b>During hospitalization</b>  |                                |                        |                           |                          |                                 |                                 |
| <b>After surgery</b>   |                                |                        |                           |                          |                                 |                                 |
| 2 wk   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| 6 wk   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| 3 mo   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Codeine phosphate and acetaminophen tablets taken over 7 postoperative days</b> |                                |                        |                           |                          |                                 |                                 |
| <b>NSAID tablets (after surgery)</b>   |                                |                        |                           |                          |                                 |                                 |
| Immediately  | ...                            | ...                    | 3 (0-6) <sup>c</sup>      | 2 (0-7) <sup>df</sup>    | ...                             | ...                             |
| 2 wk   | ...                            | ...                    | 10 (2-28) <sup>c</sup>    | 8.5 (1-28) <sup>cf</sup> | ...                             | ...                             |
| 6 wk   | ...                            | ...                    | 0 (0-28) <sup>c</sup>     | 0 <sup>df</sup>          | ...                             | ...                             |
| <b>Anal discharge<sup>l</sup></b>  |                                |                        |                           |                          |                                 |                                 |
|  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Wound discharge (after surgery)<sup>j</sup></b>                                 |                                |                        |                           |                          |                                 |                                 |
| 2 wk   | ...                            | ...                    | 20                        | 7 <sup>f</sup>           | ...                             | ...                             |
| 6 wk   | ...                            | ...                    | 0                         | 0 <sup>f</sup>           | ...                             | ...                             |
| 3 mo   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Time to wound healing, d</b>  |                                |                        |                           |                          |                                 |                                 |
|  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Unhealed wounds at 6 wk</b>   |                                |                        |                           |                          |                                 |                                 |
|  | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Tenderness to PR examination (after surgery)<sup>j</sup></b>                    |                                |                        |                           |                          |                                 |                                 |
| <b>Moderate</b>  |                                |                        |                           |                          |                                 |                                 |
| 6 wk   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| 3 mo   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Severe</b>  |                                |                        |                           |                          |                                 |                                 |
| 6 wk   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| 3 mo   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |
| <b>Incontinence score</b>  |                                |                        |                           |                          |                                 |                                 |
| Preoperative   | ...                            | ...                    | ...                       | ...                      | 1.0 (0)                         | 1.0 (0)                         |
| Postoperative (6 wk)   | ...                            | ...                    | ...                       | ...                      | 1.04 (0.2)                      | 1.00 (0) <sup>l</sup>           |
| <b>Anal resting pressure, mm Hg</b>  |                                |                        |                           |                          |                                 |                                 |
| <b>Before surgery</b>  |                                |                        |                           |                          |                                 |                                 |
|  | 47.2 (39.8)                    | 51.4 (45.5)            | ...                       | ...                      | 79 (18)                         | 86 (14)                         |
| <b>After surgery</b>   |                                |                        |                           |                          |                                 |                                 |
| 6 wk   | ...                            | ...                    | ...                       | ...                      | 78 (16)                         | 83 (17)                         |
| 3 mo   | 45.2 (36.6)                    | 49.9 (40.5)            | ...                       | ...                      | ...                             | ...                             |
| 6 mo   | ...                            | ...                    | ...                       | ...                      | ...                             | ...                             |

| Ho et al <sup>14</sup>          |                                  | Mehigan et al <sup>7</sup>     |                                  | Rowell et al <sup>15</sup> |                          | Shalaby and Desoky <sup>10</sup> |                         |
|---------------------------------|----------------------------------|--------------------------------|----------------------------------|----------------------------|--------------------------|----------------------------------|-------------------------|
| CNV<br>(n = 62)                 | St<br>(n = 57)                   | CNV<br>(n = 20)                | St<br>(n = 20)                   | CNV<br>(n = 11)            | St<br>(n = 11)           | CNV<br>(n = 100)                 | St<br>(n = 100)         |
| 11.4 (9.8)                      | 17.6 (7.1) <sup>b</sup>          | ...                            | ...                              | 14.8 (3.3)                 | 14.1 (6.5)               | 19.7 (4.7)                       | 9.0 (2.7) <sup>b</sup>  |
| 2.0 (0.8) [1-4] <sup>q</sup>    | 2.1 (0.8) [2-6] <sup>q</sup>     | 1 (0-3) <sup>c</sup>           | 1 (0-4) <sup>ch</sup>            | 2.8 (0.3)                  | 1.1 (1.0) <sup>b</sup>   | 2.2 (0.5)                        | 1.1 (0.2) <sup>b</sup>  |
| 22.9 (14.2) [2-52] <sup>q</sup> | 17.1 (14.3) [0-40] <sup>qg</sup> | 34 (14-90) <sup>c</sup>        | 17 (3-60) <sup>mc</sup>          | 16.9 (7.7)                 | 8.1 (5.1)                | 53.9 (5.8)                       | 8.2 (1.9) <sup>b</sup>  |
| 4.8                             | 0                                | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 5.0 (3.1) [0-10] <sup>q</sup>   | 4.5 (3.0) [0-10] <sup>q</sup>    | ...                            | ...                              | ...                        | ...                      | 2.5 (1.3)                        | 7.6 (0.7)               |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | 0.4 (0.7)                        | 2.6 (0.6) <sup>b</sup>  |
| ...                             | ...                              | 6.5 (1-8.5) <sup>c</sup>       | 2.1 (0.2-7.6) <sup>bc</sup>      | ...                        | ...                      | ...                              | ...                     |
| 4.8 (3.1) [0-10] <sup>q</sup>   | 3.8 (3.8) [0-10] <sup>q</sup>    | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | 0.7 (-1.8 to 3.4) <sup>c</sup> | -2.8 (-9.4 to 1.3) <sup>bc</sup> | ...                        | ...                      | ...                              | ...                     |
| 4.8                             | 1.8                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 3.0 (1.9) [0-5] <sup>q</sup>    | 3.0 (2.1) [0-7] <sup>q</sup>     | ...                            | ...                              | ...                        | ...                      | 6.6 (1.2)                        | 1.1 (0.3) <sup>b</sup>  |
| 5.1 (3.2) [0-10] <sup>q</sup>   | 2.6 (3.0) [0-10] <sup>qk</sup>   | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 11.3                            | 22.8                             | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | 30                             | 55                               | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | 3.7 (0.8)                        | 0.8 (0.1) <sup>b</sup>  |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | 100                              | 49                      |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 0.3 (0.8) [0-2] <sup>q</sup>    | 0.6 (0.8) [0-1] <sup>q</sup>     | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 2.8 (9.4) [0-15] <sup>q</sup>   | 2.7 (9.8) [1-8] <sup>q</sup>     | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 19.0 (18.9) [0-64] <sup>q</sup> | 16.7 (11.3) [0-40] <sup>qk</sup> | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 1.1 (5.5) [0-42] <sup>q</sup>   | 0 <sup>d</sup>                   | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 0                               | 0                                | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | 22.9 (18.8)                | 10.6 (19.3) <sup>l</sup> | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | 10                             | 10                               | ...                        | ...                      | 14                               | 2 <sup>b</sup>          |
| 22.6                            | 14.0                             | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 4.8                             | 0                                | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 3.2                             | 0                                | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | 30.5 (5.8)                       | 7.0 (1.2) <sup>b</sup>  |
| 14.5                            | 0                                | ...                            | ...                              | 27                         | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 32.3                            | 18                               | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 3.2                             | 3.4                              | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 16.1                            | 0 <sup>d</sup>                   | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 3.2                             | 0                                | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 0.06 (0.47) [0-4] <sup>q</sup>  | 0                                | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 0.3 (1.57) [0-6] <sup>q</sup>   | 0.06 (0.45) [0-2] <sup>qo</sup>  | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 73.2 (34.6)                     | 67.2 (22.6)                      | ...                            | ...                              | ...                        | ...                      | 60.1 (6.1)                       | 61.9 (7.1)              |
| 55.3 (29.9)                     | 77.2 (163.1) <sup>f</sup>        | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| 52.7 (63.0)                     | 59.9 (36.2) <sup>f</sup>         | ...                            | ...                              | ...                        | ...                      | ...                              | ...                     |
| ...                             | ...                              | ...                            | ...                              | ...                        | ...                      | 42.7 (4.6)                       | 60.3 (6.3) <sup>m</sup> |

(continued)

**Table 6. Summary of Efficacy Results<sup>a</sup> (cont)**

| Efficacy Outcomes                               | Boccasanta et al <sup>13</sup> |                          | Brown et al <sup>12</sup> |                | Ganio et al <sup>11</sup> |                 |
|---|--------------------------------|--------------------------|---------------------------|----------------|---------------------------|-----------------|
|   | CNV<br>(n = 40)                | St<br>(n = 40)           | CNV<br>(n = 15)           | St<br>(n = 15) | CNV<br>(n = 50)           | St<br>(n = 50)  |
| Anal squeeze pressure, mm Hg                    |                                |                          |                           |                |                           |                 |
| Before surgery                                  | 97.4 (23.4)                    | 99.3 (32.9) <sup>f</sup> | ...                       | ...            | 146 (45)                  | 150 (45)        |
| After surgery                                   |                                |                          |                           |                |                           |                 |
| 6 wk  | ...                            | ...                      | ...                       | ...            | 14.3 (47)                 | 154 (50)        |
| 3 mo  | 94.7 (22.8)                    | 96.7 (30.4) <sup>f</sup> | ...                       | ...            | ...                       | ...             |
| 6 mo  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| Prolapse (after surgery) <sup>g</sup>           |                                |                          |                           |                |                           |                 |
| 2 wk  | ...                            | ...                      | 0                         | 7 <sup>l</sup> | ...                       | ...             |
| 6 wk  | ...                            | ...                      | 0                         | 0 <sup>l</sup> | ...                       | ...             |
| 1 y   | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| Self-reported, at a mean of 16 (range, 8-19) mo |                                |                          |                           |                |                           |                 |
| Rare  | ...                            | ...                      | ...                       | ...            | 6                         | 16 <sup>o</sup> |
| Frequent  | ...                            | ...                      | ...                       | ...            | ...                       | 4               |
| Acrochordons <sup>h</sup>                       |                                |                          |                           |                |                           |                 |
| Independently observed (after surgery)          |                                |                          |                           |                |                           |                 |
| 2 wk  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| 6 wk  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| 3 mo  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| Patient observed (after surgery)                |                                |                          |                           |                |                           |                 |
| 2 wk  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| 6 wk  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| 2-3 mo  | 5                              | 2.5 <sup>f</sup>         | ...                       | ...            | ...                       | ...             |
| Pruritus (after surgery) <sup>j</sup>           |                                |                          |                           |                |                           |                 |
| 2 wk  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| 6 wk  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| 3 mo  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| Patient satisfaction                            |                                |                          |                           |                |                           |                 |
| During hospitalization (after surgery)          |                                |                          |                           |                |                           |                 |
| 1-2 wk  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| 6 wk  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| 3 mo  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| ≥10 wk after surgery <sup>j</sup>               |                                |                          |                           |                |                           |                 |
| Unsatisfactory                                  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| Satisfactory                                    | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| Good  | ...                            | ...                      | ...                       | ...            | ...                       | ...             |
| Excellent                                       | ...                            | ...                      | ...                       | ...            | ...                       | ...             |

<sup>a</sup>Data are given as mean (SD) unless otherwise indicated. CNV indicates conventional hemorrhoidectomy group; St, stapled hemorrhoidectomy group; VAS, visual analog scale; IM, intramuscular; NSAID, nonsteroidal anti-inflammatory drug; PR, per rectal; and ellipses, data not available.

<sup>b</sup>P < .001 compared with CNV.

<sup>c</sup>Data are given as median (range).

<sup>d</sup>P < .05 compared with preoperatively.

<sup>e</sup>P = .01 compared with CNV.

<sup>f</sup>Not statistically significant compared with CNV.

<sup>g</sup>Data in brackets are the range.

<sup>h</sup>P = .38 compared with CNV.

<sup>i</sup>P = .04 compared with CNV.

<sup>j</sup>Data are given as percentage of patients.

<sup>k</sup>P < .005 compared with CNV.

<sup>l</sup>P = .14 compared with CNV.

<sup>m</sup>P < .0001 compared with CNV.

<sup>n</sup>P = .03 compared with CNV.

<sup>o</sup>P = .002 compared with CNV.

stapled hemorrhoidectomy group compared with 13 to 34 days for the conventional hemorrhoidectomy groups.

### Readmission

The pooled data were inconclusive because of low event rates and small patient numbers, but suggested a trend toward a lower risk of readmission after stapled hemorrhoidectomy.<sup>12,14</sup>

### Pain and Analgesia

Pain was assessed by duration or severity, and was scored on a visual analog scale (0 indicating no pain; and 10, severe pain). Three studies<sup>10,12,14</sup> reported on the severity of pain experienced during the hospital stay, with 2 studies<sup>10,14</sup> reporting lower pain scores for the stapled hemorrhoidectomy group and 1 study<sup>12</sup> reporting the pain score was higher. Pooled data from these studies<sup>10,14</sup> were



| Ho et al <sup>14</sup> |                            | Mehigan et al <sup>7</sup> |                | Rowell et al <sup>15</sup> |                | Shalaby and Desoky <sup>10</sup> |                           |
|------------------------|----------------------------|----------------------------|----------------|----------------------------|----------------|----------------------------------|---------------------------|
| CNV<br>(n = 62)        | St<br>(n = 57)             | CNV<br>(n = 20)            | St<br>(n = 20) | CNV<br>(n = 11)            | St<br>(n = 11) | CNV<br>(n = 100)                 | St<br>(n = 100)           |
| 172.3 (86.6)           | 199.7 (80.8)               | ...                        | ...            | ...                        | ...            | 147.2 (20.7)                     | 145.4 (24.1)              |
| 176.4 (70.1)           | 172.9 (102.7) <sup>f</sup> | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 181.2 (246.5)          | 229.9 (167.6) <sup>f</sup> | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| ...                    | ...                        | ...                        | ...            | ...                        | ...            | 116.4 (14.3)                     | 142.8 (22.2) <sup>p</sup> |
| ...                    | ...                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| ...                    | ...                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| ...                    | ...                        | ...                        | ...            | ...                        | ...            | 2.5                              | 1.1                       |
| ...                    | ...                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| ...                    | ...                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 16.1                   | 19.3                       | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 4.8                    | 8.8                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 3.2                    | 3.5                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 9.7                    | 12.3                       | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 4.8                    | 7.0                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 1.6                    | 1.8                        | 5                          | 20             | ...                        | ...            | 1                                | 4                         |
| 43.5                   | 15.8 <sup>d</sup>          | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 17.7                   | 8.8                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 3.2                    | 3.5                        | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 7.4 (0.8)              | 7.3 (0.8)                  | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 6.7 (1.6)              | 6.8 (1.5)                  | ...                        | ...            | ...                        | ...            | 92 <sup>j</sup>                  | 80 <sup>i</sup>           |
| 8.3 (5.5)              | 8.0 (6.8)                  | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| 8.6 (4.7)              | 8.2 (6.0)                  | ...                        | ...            | ...                        | ...            | ...                              | ...                       |
| ...                    | ...                        | 5                          | 5              | ...                        | ...            | ...                              | ...                       |
| ...                    | ...                        | 20                         | 10             | ...                        | ...            | ...                              | ...                       |
| ...                    | ...                        | 35                         | 30             | ...                        | ...            | ...                              | ...                       |
| ...                    | ...                        | 40                         | 55             | ...                        | ...            | ...                              | ...                       |

heterogeneous and inconclusive. The third study<sup>12</sup> reported that stapling led to greater pain in the immediate postoperative period.

Postdischarge pain scores were collected at various stages of recovery. One week after surgery, the mean pain scores were 2.6 and 0.4 for the conventional and stapled techniques, respectively ( $P < .001$ ).<sup>10</sup> Pain scores up to 10 postoperative days<sup>7</sup> were higher for conventional than for stapled hemorrhoidectomy ( $P < .001$ ),<sup>7</sup> and patients in the stapled hemorrhoidectomy group experienced less pain

than they expected ( $P < .001$ ).<sup>7</sup> The findings for patients up to 2 and 6 weeks after surgery followed these general trends.<sup>12,14</sup> Other studies assessed long-term pain at 3 months<sup>14</sup> and at 8 to 19 months.<sup>11</sup> In most studies,<sup>10-12,14</sup> fewer patients reported the presence of persistent pain after stapled hemorrhoidectomy.

During hospitalization, there was no clear trend in pain experienced during discharge of feces.<sup>10,12,14</sup> However, 2 weeks after surgery, pain scores were significantly lower in the stapled hemorrhoidectomy groups.<sup>12,14</sup> More patients had

resumed their bowel function before discharge compared with those undergoing conventional surgery.<sup>14</sup> Similarly, patients who underwent the stapled procedure were almost twice as likely to have resumed their bowel function within 24 hours of surgery.<sup>7</sup> In general, less analgesia was required following stapled hemorrhoidectomy. This was shown in most studies.<sup>10,11,14,15</sup>

### Anal Discharge

At 6 months, anal discharge was more common following conventional hemorrhoidectomy in one study.<sup>10</sup> However, the new onset of passage of slime or mucus from the rectum was similar between the 2 treatment groups in another study.<sup>7</sup>

### Wound Discharge

By 6 weeks, wound discharge had ceased in all patients who had previously presented symptoms in one study,<sup>12</sup> but in the other study,<sup>14</sup> discharge continued for up to 3 months in patients who underwent conventional hemorrhoidectomy. A meta-analysis of pooled data obtained at 2 weeks postoperatively was inconclusive. Wound healing took significantly longer following the conventional intervention ( $P < .001$ ),<sup>10</sup> with fewer patients healed at 6 to 10 weeks.<sup>14,15</sup>

### Tenderness to Rectal Examination

Significantly more patients in the conventional hemorrhoidectomy group experienced moderate or severe tenderness to rectal examination at 2 and at 6 weeks postoperatively.<sup>14</sup> At 3 months, tenderness had decreased substantially in both groups, with neither intervention showing more favorable outcomes.

### Incontinence

The incidence of incontinence to gas, liquid, or solid was extremely rare in both groups of patients when assessed preoperatively and at various points in their postoperative recovery. Two studies<sup>11,14</sup> measured incontinence scores, but only one of these studies<sup>11</sup> found a significant difference between treatments in favor of the stapled hemorrhoidectomy group.

### Anal Resting and Squeeze Pressures

Studies that measured this outcome did so by anorectal manometry. Anal resting and squeeze pressures were measured preoperatively and postoperatively in 4 studies.<sup>10,11,13,14</sup> There were no significant functional variations between the measurements in both groups,<sup>11,13,14</sup> although in one study,<sup>10</sup> both pressures were significantly reduced in the conventional hemorrhoidectomy group at 6 months ( $P < .05$ ), which was not reflected in the stapled hemorrhoidectomy group.

### Prolapse

At a mean follow-up of 16 months, self-reported prolapse was more common in the stapled hemorrhoidectomy

group<sup>11</sup>; another study<sup>10</sup> reported a low incidence of prolapse at 1 year of follow-up in both treatment groups.

### Acrochordons

Pooled RRs for patient-perceived acrochordons at 2 to 3 months after surgery were inconclusive.<sup>7,10,13,14</sup> One study<sup>14</sup> reported a variation between patient-perceived postoperative acrochordons and those reported by independent assessment at 3 follow-up times. The presence of acrochordons reported by patients was less than that noted by independent assessment; overall, acrochordons were less prevalent in the conventional hemorrhoidectomy group compared with the stapled hemorrhoidectomy group.<sup>14</sup>

### Pruritus

Fewer patients experienced pruritus after stapled hemorrhoidectomy at 2 weeks postoperatively in one study.<sup>14</sup> At 3 months, there was no difference in the proportion of patients with pruritus in both treatment groups.<sup>14</sup>

### Patient Satisfaction

Several studies<sup>7,10,14</sup> assessed the level of patient satisfaction after completion of surgery. Members from the stapled hemorrhoidectomy groups perceived a higher rate of operative success than patients undergoing one of the conventional hemorrhoidectomy procedures.

## COMMENT

The RCTs available for review represented average-quality level II evidence, limited by a small sample size and short follow-up times. All were conducted during the past 6 years, but there was a significant lack of comparability between the studies. There was wide variation in patient characteristics, stapling equipment used, surgical protocol, postoperative care regimen and assessment, and methods of outcome measures. These factors must be taken into account when interpreting the results.

Stapled hemorrhoidectomy seemed to be at least as safe as conventional hemorrhoidal surgery techniques. However, the efficacy of stapled hemorrhoidectomy, compared with conventional techniques, could not be determined. This was because of the limited data available, the lack of comparability between the efficacy outcome measures, and variability in the length of follow-up conducted between the studies.

Because of the variability in outcome measures, only relatively few outcomes from a few of the studies could be pooled in a meta-analysis. There was reasonably clear evidence in favor of the stapled procedure for bleeding at 2 weeks and length of hospital stay. Other less robust results in favor of stapled hemorrhoidectomy related to pain, bleeding, anal discharge, wound healing, tenderness to per rectal examination, incontinence scores, earlier return of bowel function, analgesic requirement, and resumption of normal activities. On the other hand, one trial showed that prolapse occurred at significantly higher rates in the stapled hemorrhoidectomy group, up to 19

months after surgery. Because this is one of the indications for surgery, its persistence may be seen as treatment failure. Outcome measures for pain and bleeding varied greatly between studies, so few conclusions could be made. This is of concern because both of these symptoms are of primary importance for patients undergoing hemorrhoidectomy.

More serious complications following stapled surgery have been reported in the literature,<sup>19</sup> including one case of life-threatening pelvic sepsis. This has led some clinicians to support the use of prophylactic antibiotics.<sup>20,21</sup> There has also been one reported case of rectovaginal fistula,<sup>22</sup> which has led to the proposal that a vaginal examination should be performed routinely after closure and before firing of the stapler.<sup>5</sup> Anecdotal evidence<sup>21</sup> documenting the incidence of severe pain and fecal urgency following stapled hemorrhoidectomy also exists. It has been suggested that this can be attributed to the misplacement of the purse-string suture in relation to the dentate line,<sup>6</sup> and is likely to be avoided by standard placement of the purse-string suture at 4 cm above the dentate line, at which level the rectal mucosa is much less sensitive to pain.

With any stapling procedure, there is the possibility of instrument failure. One report<sup>23</sup> has documented a case of intraoperative failure due to a device error. Consequently, the researchers recommended the routine checking of staplers for defects before the commencement of surgery.

The costs associated with the 2 procedures are an important consideration when assessing their suitability.<sup>10,14</sup> Because the length of hospital stay was similar in both treatment groups<sup>7,10-15</sup> the price of the stapling device adds dramatically to the cost of this intervention method. This does not, however, take into account the shorter convalescence period and earlier return to normal activities that may be the case for patients after stapled hemorrhoidectomy.<sup>7,10-15</sup>

These results have recently drawn attention to the possibility of performing stapled hemorrhoidectomy as a day-case procedure under regional anesthesia.<sup>24</sup> This may decrease medical-related costs and minimize anesthesia-related complications, such as urinary retention. Four studies<sup>25-28</sup> have examined the feasibility of this, and all have reported favorable results for the stapled technique.

Several potential biases have been recognized. The devices used in the 7 RCTs<sup>7,10-15</sup> included in this review were all marketed by Ethicon Endosurgery, a division of Johnson & Johnson (Cincinnati, Ohio). The results from 3 of the RCTs<sup>7,14,15</sup> are also included in a promotional booklet produced by Ethicon Endosurgery. One of the included studies<sup>15</sup> acknowledges the use of equipment donated by Ethicon Endosurgery. Furthermore, 2<sup>12,14</sup> of the 7 RCTs were conducted at the same hospital, and 2 researchers had made contributions to both studies. This may mean that the views of these researchers have had an undue influence on the findings of this review.

Four RCTs<sup>9,28-30</sup> were not included in this review because only the abstracts from conference proceedings could be obtained, but their conclusions tended to concur with the data extracted from the included trials.

None of the included RCTs in this review thoroughly assessed the long-term safety and efficacy of the procedure. One prospective study<sup>6</sup> has followed up patients for up to 3 years, and one retrospective case series<sup>31</sup> has evaluated patient outcomes at up to 10 years after surgery.

## CONCLUSIONS

The safety and efficacy of a new surgical technique must be confirmed before it can be widely accepted into clinical practice. Stapled hemorrhoidectomy may offer some favorable outcomes that support it as an alternative to conventional techniques.

All of the RCTs available for review represented an average quality of evidence. However, the few patients treated emphasizes the need for further larger studies to be conducted.

Stapled hemorrhoidectomy seems to be a safe alternative to conventional approaches for the treatment of third- and fourth-degree hemorrhoids, and is accompanied by a significantly shorter operating time and convalescence and an earlier return to normal activities. However, the potential benefits may only appear after surgeons have gained experience with the procedure.

Because this review reports inconclusive outcomes for the efficacy of circular stapled hemorrhoidectomy, further research should be conducted in the following areas: (1) The feasibility of both techniques as day-case procedures should be determined. (2) Costs with data specific to the Australasian medical system should be determined. (3) Long-term outcomes, in particular symptom and hemorrhoidal recurrence, need to be assessed in a well-designed RCT. (4) Studies with a larger sample size should be conducted, to increase statistical power. (5) Standardization of outcome measures, particularly for pain and bleeding, is required.

The Council of the Royal Australasian College of Surgeons endorsed the following ASERNIP-S safety and efficacy classifications for stapled hemorrhoidectomy.

1. Evidence rating: average. The level II evidence was limited by the small sample size and short follow-up times. Few studies assessed similar end points, and there was incomplete reporting of important outcomes.

2. Safety. The procedure was as safe as the comparative procedure.

3. Efficacy. The efficacy cannot be determined.

It was recommended that surgeons practicing stapled hemorrhoidectomy should conduct a careful audit of their results. It was also suggested that, as a minimum requirement, surgeons wanting to use the stapled technique of hemorrhoidectomy should undergo appropriate training and supervised instruction in accordance with training guidelines developed by the Colorectal Surgical Society of Australasia. Stapled hemorrhoidectomy may be a viable addition to the therapy options available for treating hemorrhoids, but more rigorous studies with longer follow-up periods and larger sample sizes must be pursued.

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