INFORMATION BRIEF (RAPID REVIEW)

LASER HAEMORRHOIDOPEXY

Malaysian Health Technology Assessment Section (MaHTAS)
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TITLE: LASER HAEMORRHOIDOPEXY

PURPOSE

To provide brief information on the effectiveness, safety and economic implication of laser haemorrhoidopexy following request from Medical Practice Division, Ministry of Health Malaysia.

BACKGROUND

Haemorrhoids are currently recognised as a significant contributor to morbidity, with notable economic and social implications for society.[1] The prevalence of haemorrhoids in the general population is estimated to be 11%, highest in Australia at 38.93%, followed by 16% in Israel and 14.4% in Korea and majority of patients diagnosed with low-severity disease.[2,3] Approximately 40% of patients with haemorrhoidal disease consulted a medical practitioner as their initial step in the treatment process, indicating a trend of underdiagnosis and undertreatment, as well as the necessity for patients to access reliable and accurate health information from alternative sources.[3] In Malaysia, a significant association was observed between age and haemorrhoids, with individuals younger than 50 years being more likely to have haemorrhoids than those older than 50 years.[4]

Haemorrhoids are classified into internal and external haemorrhoids in relation to the dentate line. Internal haemorrhoids are further classified into grade I to IV based on degree of prolapse, facilitating targeted treatment interventions. Some risk factors of haemorrhoids include age, pregnancy, chronic diarrhoea, chronic constipation, obesity, prolonged sitting and genetics. Manifestation of symptomatic internal haemorrhoids includes painless bright red bleeding, prolapse, soiling, bothersome grape-like tissue prolapse, itching, or a combination of these symptoms. External hemorrhoids may resemble internal haemorrhoids; however, they can become painful, particularly when thrombosed.[5,6] The most frequent complications of haemorrhoids include perianal thrombosis and incarcerated prolapsed internal haemorrhoids followed by thrombosis.[3] The implications of haemorrhoids extend beyond mere physical discomfort and can have profound negative impact on the quality of life of an individual due to the resulting pain, itching and bleeding.[7]

Treatment modalities available for haemorrhoids are tailored according to the severity of the condition, classified into pharmacological therapies, non-pharmacological interventions, outpatient procedures, and surgical treatments.[8] First-line conservative treatment of haemorrhoids consists of a high-fiber diet (25 to 35 g per day), fiber supplementation, increased water intake, sitz baths and stool softeners.[6] While conservative or medical therapy is often the initial treatment approach, ongoing symptoms such as rectal bleeding, pain, itching, and tissue prolapse may necessitate procedural interventions.[9]

The surgical treatment options for haemorrhoids include rubber band ligation, injection sclerotherapy, transanal haemorrhoidal dearterilization, stapled hemorrhoidopexy, laser photocoagulation, haemorrhoidectomy and stapled haemorrhoidectomy.[5,10] The primary goals of surgical haemorrhoidectomy are to excise the symptomatic haemorrhoidal columns, reduce the excess tissue responsible for haemorrhoidal tissue prolapse (mucopexy), and to minimize pain and complications.[6] Milligan-Morgan haemorrhoidectomy is considered to be the gold standard treatment for haemorrhoid and is the most widely practiced surgical procedure. Nevertheless, patients can experience short term complications such as postoperative pain, haemorrhage, urinary retention, and abscess formation as well as long-term complications including stool incontinence, fistula formation and stenosis.[10]

Laser haemorrhoidopexy is a novel modification of laser haemorrhoidoplasty for haemorrhoids of all grades, especially Grade II and Grade III as shown in Figure 1. This technique involves laser energy which is applied to the surface of the mucosa via the natural anal canal, as opposed to the submucosal plane used in haemorrhoidoplasty. Laser haemorrhoidopexy seeks to achieve a mucopexy effect through the application of laser energy, resulting in either circumferential or linear mucosal ablation. The energy used for mucosal ablation is minimal at about 50 to 100 joules for each haemorrhoidal pedicle, thus reducing the risk of mucosal haematoma linked to laser haemorrhoidoplasty where 200–250 joules of energy per pedicle is utilised. Only in several cases associated with significant internal mucosal prolapse, suture haemorrhoidopexy is done along with laser haemorrhoidopexy.[11]

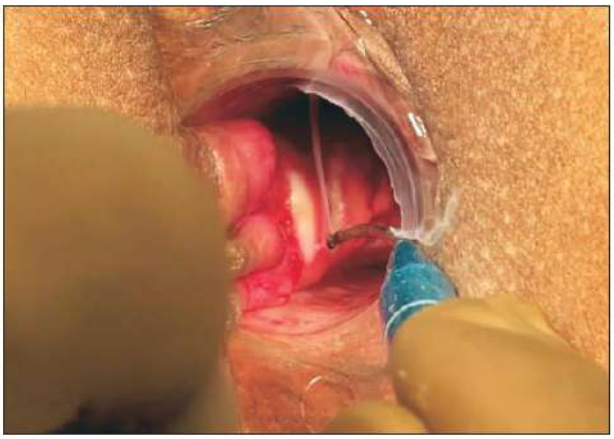

Figure 1: Laser haemorrhoidopexy 2cm above the apex of haemorrhoids and at the apex of hemorrhoids.[2]

Figure 2: Grade III haemorrhoids before and after laser haemorrhoidopexy

EVIDENCE SUMMARY

A systematic review was conducted and search strategy was developed by the main author. The following electronic databases were searched through the Ovid interface: MEDLINE® All <1946 to 25th October 2024>. Comparative searches were run in PubMed, Cochrane and INAHTA databases as well as Google Scholar. To achieve comprehensive literature saturation, references cited in the retrieved articles were also reviewed and assessed for eligibility. The search was limited to articles on human and there was no language limitation. The last search was carried out on 28th October 2024. There were two studies included in this review which comprised of one cohort study[11] and one case report.[12]

EFFECTIVENESS

A prospective cohort study was conducted by Porwal et al. (2023) to evaluate the effectiveness and long-term outcomes of laser haemorrhoidopexy. The outcomes measured includes perioperative complications, recurrence rate and patient satisfaction using validated questionnaire. This study included 1,088 patients who underwent laser haemorrhoidopexy at a single center in India from June 2014 to December 2018. The majority of patients (68. 0%) were male, with most patients falling within the 31 to 40 age range. Out of the 1088 patients, 840 patients (77.2%) were diagnosed with grade II haemorrhoids, with 17% of these cases being associated with internal mucosal prolapse. Consequently, further suture mucopexy was carried out for individuals with internal mucosal prolapse. The predominant preoperative symptoms included anal bleeding in 83.3% of patients, perianal pain in 17.1%, constipation in 22.5%, and itching and discharge in 6.4%. The average length of hospital stay was 16.1 hours, with a range of 12 to 30 hours, and no significant intraoperative complications were documented. The study found that the recurrence rate was 0.55%, with only six patients with grade III haemorrhoids who experienced recurrence after a median follow-up of 48 months. No recurrence was reported in patients with grade II haemorrhoids. The overall patient satisfaction was high, with 94.21% expressing satisfaction with the outcome of laser hemorrhoidopexy.[11]

In a case report authored by Goyal et al. (2023), laser haemorrhoidopexy was utilized for the management of grade IV haemorrhoids in a 66-years-old female patient with concomitant acute myeloid leukemia and severe thrombocytopenia. This study aimed to assess the postoperative pain and recurrence up to 1 year in a patient diagnosed with grade IV haemorrhoids. The study found that postoperative outcomes were favourable with minimal pain, rapid recovery and no need for additional interventions. The postoperative pain was assessed using a visual analogue scale (VAS), showing a decrease from 5 out 10 on day 1 to 2 out 10 on day 7 and 0 out 10 by day 14. The patient resumed her daily activities by day 3, experienced a significant reduction in haemorrhoid size within days and achieved complete resolution by six weeks. There was no recurrence or bleeding recorded during follow-ups up to one year.[12]

SAFETY

Medical device lasers are classified as class IV laser hazard by the US Food and Drug Administration (FDA).[13] Th[redacted] developed by [redacted] is a class 4 medical laser according to Directive EN 60825-1:2003 and is a device commonly used for laser haemorrhoidoplasty. This device bears the CE mark but is yet to gain US Food and Drug Administration (FDA) approval. Only the [redacted] Laser has obtained 510(k) clearance from the US Food and Drug Administration (FDA).[14,15,16]

Among the complications related to laser haemorrhoidopexy were minor bleeding and urinary retention experienced in early postoperative stages. As for late postoperative complications, about 2.5% to 3.6% patients had bleeding which was the most common complications. Other complications included persistent pain, external thrombosis and fissure-in-ano. However, none of the above complications were life-threatening.[11]

ECONOMIC IMPLICATION

There was no retrievable evidence on the cost-effectiveness or other economic analysis related to laser haemorrhoidopexy, nor was there any information retrieved on the cost of this procedure.

CONCLUSION

There is limited evidence on effectiveness and safety of laser haemorrhoidopexy in the treatment of patients with haemorrhoids. Evidence demonstrated its potential in no recurrence and high satisfaction in patients with grade II haemorrhoids up to 1 year, and it is considered safe with only minor complications observed.

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