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HARMONIC SCALPEL® HEMOROIDEKTOMIJA - BEZBOLNA PROCEDURA?

HARMONIC SCALPEL® HEMORRHOIDECTOMY: A PAINLESS PROCEDURE?

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Sažetak - Lečenje hemoroida praćeno je izraženim bolom, zbog čega se novijim istraživanjima tražila modifikacija standardne Milligan-Morganove metode lečenja. U novijoj literaturi, po iskustvima autora, nova metoda *Harmonic Scalpel*® hemoroidektomija daje manji postoperativni bol. Cilj ovog rada bio je da se statistički proceni, na osnovu naših iskustava, uspešnost postoperativnog toka pri lečenju hemoroida a u pogledu smanjenja bola i sigurnije hemostaze. Na Klinici je operisano, u poslednjih pet godina, 77 pacijenata sa III i IV stadijumom hemoroidalne bolesti. Postoperativni bol je ispitivan na osnovu vizuelne analogne skale bola, tokom prvog, drugog i sedmog postoperativnog dana u dve grupe bolesnika, određivane u odnosu na metod operacije. Statistička obrada podataka izvršena je pomoću programskog softvera *Statistica 7.0*. Zaključeno je da je *Harmonic Scalpel*® hemoroidektomija, zbog smanjenog termičkog oštećenja, dala statistički dokazano smanjenu bolnost, obezbedila bolju hemostazu, uz manji broj urinarnih komplikacija, u odnosu na Milligan-Morganov metod lečenja ove bolesti.

Cljučne reči: Hemoroidi + hirurgija; Postoperativni bol; Hirurške tehnike digestivnog trakta + metode

Summary - Since the surgical treatment of hemorrhoidal disease has been characterized by intense postoperative pain, recent studies have tried to modify the standard Milligan-Morgans technique. The up-to-date literature, in the experience of authors, has confirmed that the new method of *Harmonic Scalpel*® hemorrhoidectomy reduces postoperative pain. The aim of our study was to statistically evaluate, based on our experience, the efficacy of this surgical approach in terms of reducing postoperative pain and establishing a stable hemostasis. Seventy-seven (77) patients suffering from hemorrhoidal disease, stage III and IV, underwent surgery in our clinic during the last five years. The postoperative pain was determined using the visual analog scale on the 1st, 2nd and 7th postoperative days. Patients were divided into two groups in regard to the surgical procedure applied. The data were statistically processed using the *Statistica 7.0* software. We concluded that *Harmonic Scalpel*® hemorrhoidectomy, due to less thermal damage, statistically significantly reduced postoperative pain with better hemostasis, compared with Milligan-Morgan's method of treating hemorrhoidal disease.

Key words: Hemorrhoids + surgery; Pain, Postoperative; Digestive System Surgical Procedures + methods

Uvod

Hemoroidektomija je izuzetno bolna procedura. Bol nakon hemoroidektomije uzrokovan je oštećenjem tkiva analne regije, bogate nervnim završecima, tokom hirurškog zahvata. Smanjenje postoperativnog bola pokušano je perioperativnom upotrebom različitih analgetika, modifikacijama hirurške tehnike hemoroidektomije i korišćenjem novih hirurških instrumenata i aparata [1-4].

Nedavnim studijama dokazano je da ultrazvučne makaze *Harmonic Scalpel*® aparata (*Ethicon EndoSurgery, Cincinnati, OH, USA*) tokom disekcije tkiva stvaraju relativno nisku temperaturu [5,6]. Niža temperatura pri kojoj se obavlja disekcija, smanjuje i termičko oštećenje okolnih struktura. Zbog manje destrukcije tkiva osetljive analne regije, hemoroidektomija ultrazvučnim makazama *Harmonic Scalpel*® aparata mogla bi da smanji postoperativni bol.

Cilj nam je da dokažemo uspešnost *Harmonic Scalpel*® (HS) hemoroidektomije u smanjenju postoperativnog bola a u odnosu na klasičnu Milligan-

Introduction

Hemorrhoidectomy is an extremely painful procedure. Pain that occurs after hemorrhoidectomy is caused by the damage done to the tissues in the anal region, rich in nerve endings, during the surgical procedure. There have been various approaches to the reduction of pain after hemorrhoidectomy: use of a variety of painkillers during and after the surgery, modifications of the hemorrhoidectomy technique or use of the latest surgical instruments and appliances [1-4].

Recent studies have shown that ultrasound scissors, *Harmonic Scalpel*® (*Ethicon EndoSurgery, Cincinnati, OH, USA*) generates a relatively low temperature during tissue dissection [5,6]. Lower temperature during dissection reduces the damage to the surrounding tissues caused by heat. Reduced destruction of tissues in the sensitive anal region, as a result of hemorrhoidectomy performed by *Harmonic Scalpel*®, may reduce the postoperative pain.

Our aim is to prove the superiority of hemorrhoidectomy performed by *Harmonic Scalpel*® (HS) in

Skraćenice

HS	- <i>Harmonic Scalpel®</i>
MM	- Milligan-Morgan

Morganovu hemoroidektomiju (MM). Prospektivna klinička studija trebalo bi da ukaže na smanjenje bola nakon HS hemoroidektomije, i da na taj način olakša i pacijentima i hirurzima donošenje odluke o definitivnom lečenju uznapredovalih stadijuma hemoroidalna bolest.

Materijal i metode

U Klinici za abdominalnu i endokrinu hirurgiju Instituta za hirurgiju Kliničkog centra u Novom Sadu, od decembra 2001. do novembra 2005. godine, zbog hemoroida operisano je 77 pacijenata. U istraživanje su uključeni pacijenti sa oboljenjem hemoroida trećeg (hemoroidi koji prolaboraju pri defekaciji ili napinjanju i zahtevaju manuelnu repoziciju) ili četvrtog stepena (hemoroidi su stalno van analnog kanala i njihova repozicija nije moguća). Pacijenti su operisani u elektivnom operativnom programu u 29 slučajeva odnosno 37,7%. Zbog komplikacija bolesti (izraženog krvarenja, tromboze hemoroida), 48 pacijenata (62,3%) operisano je tokom dežurstava. U studiju nisu uključeni pacijenti mlađi od 18 godina kao i pacijenti koji su pored oboljenja hemoroida imali i neko drugo oboljenje analne regije (fisuru, fistulu, perianalni apsces).

Pacijenti operisani u elektivnom operativnom programu hospitalizovani su dan pre operacije, dok su pacijenti u urgentnom programu operisani nakon kratke preoperativne pripreme, tokom istog dana. Hemoroidektomija je izvođena u spinalnoj anesteziji.

Pacijenti su bili informisani o operaciji i njenim komplikacijama i dali su pismeni pristanak za njeno izvođenje i ispitivanje. Randomizacija pacijenata je izvedena na osnovu kompjuterskog programa a neposredno pre odlaska u operacionu salu.

Prvu grupu pacijenata činili su bolesnici sa bolešću hemoroida kod kojih je izvedena *Harmonic Scalpel®* hemoroidektomija koja predstavlja modifikaciju Milligan-Morganove hemoroidektomije (odstranjenje tri nodusa na tipičnim mestima - na 3, 7 i 11 sati). Modifikacija se odnosi na upotrebu ultrazvučnih makaza - *Coagulating Shears®* modela za otvorenu hirurgiju, 14 cm/5 mm (*Ethicon Endo-Surgery, Cincinnati, OH, USA*). U drugoj grupi su bili pacijenti kod kojih je izvedena Milligan-Morganova hemoroidektomija, na način opisan u originalnom radu ovih autora [7].

Ispitivan je postoperativni bol na osnovu vizuelne analogne skale bola, a način njene primene je objašnjen pacijentima preoperativno. Stepen bola je rangiran od 0 (nema bola) do 10 (veoma jak bol). Postoperativni bol kod pacijenata je beležen prvog, drugog i sedmog postoperativnog dana. Pacijenti su tokom prva dva postoperativna dana primali ampule diklofenaka na svaka četiri sata, a po otpustu iz

Abbreviations

HS	- <i>Harmonic Scalpel®</i>
MM	- Milligan-Morgan

reducing postoperative pain compared to the classical Milligan-Morgan's (MM) technique. The purpose of this prospective clinical study was to examine postoperative pain in HS hemorrhoidectomy and thus make it easier for both patients and surgeons to decide on the way of treatment for advanced cases of hemorrhoidal disease.

Material and Methods

In the period from December 2001 to November 2005, seventy-seven patients were operated on for hemorrhoid problems at the Clinic of Abdominal and Endocrine Surgery, Institute of Surgery, Clinical Center in Novi Sad. Our research included patients with hemorrhoidal disease with stage III hemorrhoids (hemorrhoids protrude with stool and must be manually reduced) and stage IV (hemorrhoids chronically prolapse and cannot be reduced). Twenty-nine patients (37.7%) had elective surgery. Forty-eight patients (62.3%) had emergency surgery, due to certain complications such as bleeding or hemorrhoidal thrombosis. This study did not include patients under 18 years of age or patients with anal diseases other than hemorrhoidal disease, such as fissures, fistulas or perianal abscess.

Patients having elective surgery were admitted the day before surgery, while patients having emergency surgery underwent surgery following a short preoperative waiting time on the day of admittance. Hemorrhoidectomy was carried out under spinal anesthesia.

All patients were fully informed about the procedure and possible complications and they gave a written consent. Patients were randomized by a computer-generated schedule immediately before surgery. The first group consisted of patients undergoing *Harmonic Scalpel®* hemorrhoidectomy, which is a modification of the Milligan-Morgan hemorrhoidectomy (three nodes removed, typically at three, seven and eleven o'clock). Modification consisted of the use of ultrasound scissors, *Coagulating Shears®*, designed for open surgery, 14 cm/5 mm (*Ethicon Endo-Surgery, Cincinnati, OH, USA*). The second group included patients undergoing Milligan-Morgan hemorrhoidectomy, the way two authors originally described it in their paper [7].

The study investigated postoperative pain based on a visual analog scale. The way it was to be applied was explained to patients before surgery. The level of pain ranged from 0 (no pain) to 10 (very strong pain), and it was measured on the first, second and seventh days after surgery. Patients received vials of diclofenac at four hour intervals during the first two days after surgery. It was recommended to them to continue with therapy after leaving the hospital but in the form of dragees.

The study also examined postoperative complications following both types of procedures.

bolnice preporučena im je primena diklofenaka u obliku dražeja.

Posmatrane su i postoperativne komplikacije nakon obe metode hemoroidektomije.

Statistička obrada podataka izvršena je pomoću programskog softvera *Statistica 7.0*. Za određivanje statistički signifikantne razlike je u svim testovima uzet nivo poverenja $\alpha = 0,05$.

Rezultati

Testirana je homogenost grupe pacijenata kod kojih je izvedena *Harmonic Scalpel*® hemoroidektomija, i grupe pacijenata kod kojih je izvedena Milligan-Morganova hemoroidektomija, a u odnosu na broj godina pacijenata. Mann-Whitneyev U-test je dao p-vrednost jednaku sa 0,460470, što ukazuje na činjenicu da su grupe bile homogene po godinama. Srednja vrednost godina pacijenata u HS grupi je iznosila 46,2 godine, a u MM grupi 44,98 godina. Takođe je testirana i homogenost ove dve grupe u odnosu na pol pacijenata, χ^2 -testom utvrđena je p-vrednost jednaka sa 0,8634, što pokazuje da su grupe bile ravnomerne i po ovom kriterijumu. HS metodom je izvršena hemoroidektomija kod 26 pacijenata muškog pola i 9 pacijenata ženskog pola, dok je MM metodom izvršena hemoroidektomija kod 33 pacijenta muškog pola i 9 pacijenata ženskog pola.

Podaci o stepenu bola u prvom, drugom i sedmom danu nakon operacije pokazali su da je stepen bola u obe grupe tokom vremena opadao (grafikoni 1 i 2). U grupi HS pacijenata u prvom danu stepen bola se kretao u granicama od 3 do 8 sa srednjom vrednošću 5,11, u drugom danu od 2 do 5 sa srednjom vrednošću 3,03, a u sedmom danu od 0 do 3 sa srednjom vrednošću 1,03. U grupi MM pacijenata u prvom danu stepen bola se kretao u granicama od 5 do 9 sa srednjom vrednošću 7,12, u drugom danu od 3 do 7 sa srednjom vrednošću 4,52, a u sedmom danu od 2 do 4 sa srednjom vrednošću 2,88 (grafikoni 3, 4, 5).

U svakom od navedena tri dana, srednja vrednost stepena bola pacijenata bila je statistički značajno veća u grupi pacijenata kod kojih je hemoroidektomija vršena MM metodom, u odnosu na grupu pacijenata kod kojih je hemoroidektomija vršena HS metodom. Statistički signifikantna razlika utvrđena je Kruskal-Wallisovom neparametarskom analizom varijanse (ANOVA), a p-vrednost je za sva tri dana bila jednaka nuli.

Analizirane su i postoperativne komplikacije (urinarna retencija i krvarenje) nakon obe metode hemoroidektomije. Urinarna retencija se javila kod tri pacijenta nakon HS, a kod devet pacijenata nakon MM hemoroidektomije. Urinarna retencija je rešavana plasiranjem urinarnog katetara na 24 sata. Postoperativno krvarenje se javilo samo u jednom slučaju nakon HS hemoroidektomije i zbrinuto je konzervativnim lečenjem. Kod MM metode hemoroidektomije krvarenje se javilo u sedam slučajeva,

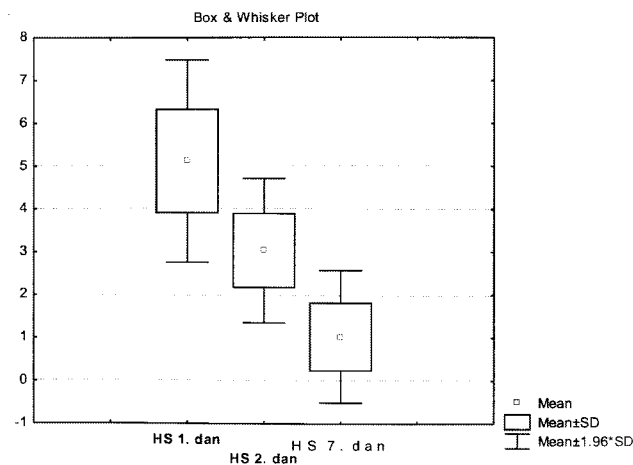
Statistica 7.0 software was used to compile the statistics. Level of trust was taken to determine statistically significant differences in all the tests.

Results

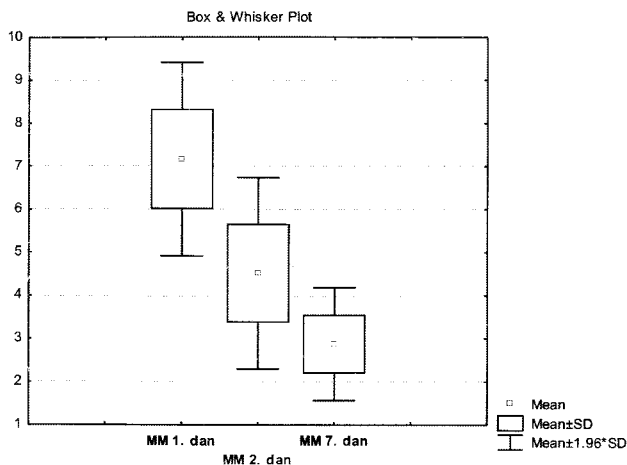
The two groups of patients, the one undergoing *Harmonic Scalpel*® hemorrhoidectomy and the one undergoing Milligan-Morgan hemorrhoidectomy, were homogeneous with respect to age. Mann-Whitney U-test gave a p value of 0.460470, which points to the fact that the two groups were homogeneous with respect to age. The average age of patients in the HS group was 46.2 years, while in the MM group it was 44.98. The two groups were also homogenous with respect to sex ($p = 0.8634$). HS procedure was used in 26 male and 9 female patients, while MM procedure was used in 33 male and 9 female patients.

The level of pain on the first, second and seventh days after operation showed decrease in pain over time in both groups (figures 1 and 2). In the HS group, the level of pain on the first day was between 3 and 8, average value 5.11, on the second day between 2 and 5, average value 3.03, and on the seventh day between 0 and 3; average value 1.03. In the MM group of patients the level of pain on the first day was between 5 and 9, average value 7.12; on the second day between 3 and 7, average value 4.52, and on the seventh day between 2 and 4, average value 2.88 (pain level distribution for HS/MM procedures is presented in figures 3, 4 and 5).

On each of the three days the average pain score was statistically significantly higher in the group of patients who underwent MM hemorrhoidectomy than in the group of patients who underwent HS hemorrhoidectomy. A statistically significant difference was determined by Kruskal-Wallis nonparametric analysis (ANOVA) with $p = 0$ on all three days.



Grafikon 1. Stepen bola pacijenata (vizuelna analogna skala bola) posle *Harmonic Scalpel*® hemoroidektomije po danima
Graph 1. Pain scores (visual analog scores) after *Harmonic Scalpel*® hemorrhoidectomy by days

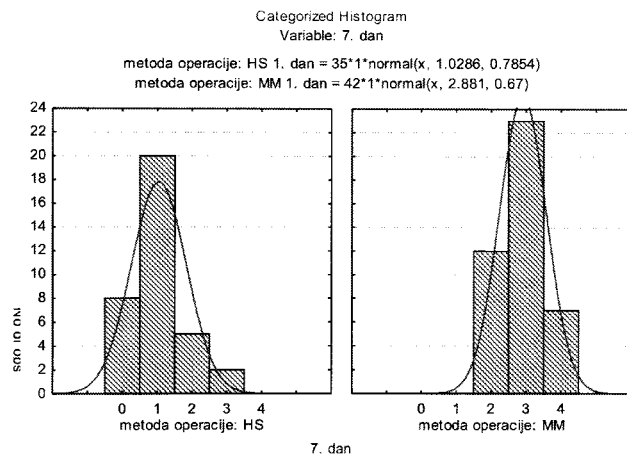


Grafikon 2. Stepen bola pacijenata (vizuelna analogna skala bola) posle Milligan-Morganove hemoroidektomije po danima
Graph 2. Pain scores (visual analog scores) after Milligan-Morgan's hemorrhoidectomy by days

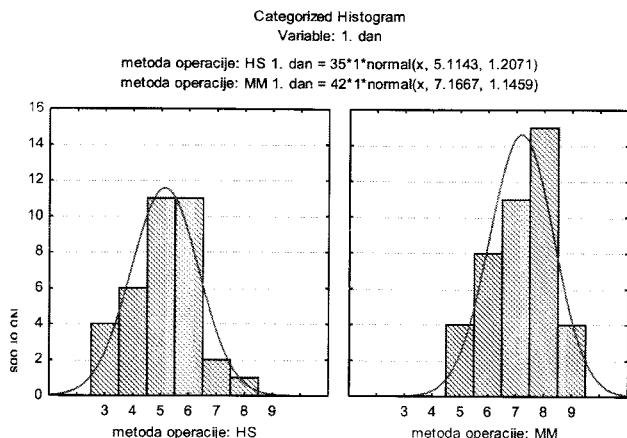
pri čemu se kod dva pacijenta moralo pristupiti operativnom zbrinjavanju krvarenja. Fišerovim egzaktnim testom (*Fisher's exact test*) izračunata je p-vrednost jednaka sa 0,6186, što pokazuje da na osnovu analiziranog uzorka nema statistički značajne zavisnosti između vrste komplikacije i metode hemoroidektomije.

Diskusija

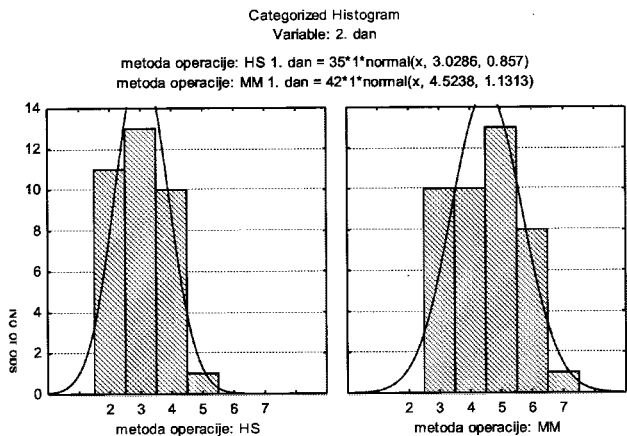
Kod bolesti hemoroida, trećeg stadijuma, sa izraženim spoljnim hemoroidnim nodusima i četvrtog stadijuma, indikovano je operativno lečenje. Milligan-Morganov koncept hemoroidektomije još uvek predstavlja "zlatni standard" u hirurškom lečenju hemoroida [7]. S obzirom na to da MM hemoroidektomija dovodi do izraženog postoperativnog



Grafikon 5. Raspodela stepena bola pacijenata u sedmom postoperativnom danu posle HS/MM hemoroidektomije
Graph 5. Pain score distribution among patients on 7th post-operative day after HS/MM hemorrhoidectomy
 HS - Harmonic Scalpel®, MM - Milligan-Morgan



Grafikon 3. Raspodela stepena bola pacijenata u prvom postoperativnom danu posle HS/MM hemoroidektomije
Graph 3. The postoperative pain score distribution among patients on the 1st day after HS/MM hemorrhoidectomy



Grafikon 4. Raspodela stepena bola pacijenata u drugom postoperativnom danu posle HS/MM hemoroidektomije
Graph 4. The postoperative pain score distribution among patients on the 2nd day after HS/MM hemorrhoidectomy

We have also analyzed postoperative complications (urinary retention and hemorrhaging) after each method of hemorrhoidectomy. Urinary retention occurred in three patients after HS procedure and in nine patients after MM procedure. Urinary retention was managed by placing an urinary catheter for 24 hours. Postoperative hemorrhaging occurred in one patient after the HS procedure and was dealt with using conservative treatment. Post-operative hemorrhaging occurred in seven cases after MM procedure, two of which were managed surgically. Fisher's exact test gave a p value of 0.6186. The result tells us that there is no statistically significant link between the complication and the type of hemorrhoidectomy.

Discussion

Surgical treatment is indicated for hemorrhoids stage III (with prominent outer hemorrhoidal nodes),

bola, pokušane su razne modifikacije ove metode. Krenulo se sa tehničkim modifikacijama kao što su delimično ili potpuno zatvaranje sluznice nakon ekscizije hemoroidalnih nodusa, ili dodavanjem unutrašnje lateralne sfinkterotomije. Napretkom tehnike i tehnologije upotrebljavani su različiti aparati - elektrokauter, dopler-aparat, stapler i laser [4,8,9].

Poslednjih godina u literaturi su se pojavili radovi nekoliko autora [10,11], koji opisuju smanjenu bolnost nakon HS hemoroidektomije. Imajući u vidu iskustva pomenutih autora, primenili smo ovu metodu i na našoj klinici. Petogodišnjim iskustvom lečenja hemoroida ovom metodom, potvrdili smo smanjeni postoperativni bol nakon HS hemoroidektomije a u odnosu na MM metodu. Smanjenje bola je bilo statistički značajno prve nedelje nakon operacije. Na smanjenje osećaj bola nakon HS hemoroidektomije ukazuje i manji broj urinarnih retencija, iako statistički nesignifikantan.

Ako se bolnost nakon MM hemoroidektomije mogla objasniti postavljanjem ligature na vaskularnu peteljku hemoroida, onda je značajno termičko oštećenje osetljive perihemoroidne regije svakako uzrok kod hemoroidektomije elektrokauterom i laserom. Smanjenje ovog termičkog oštećenja smatra se osnovnim uzrokom smanjenja bola nakon HS hemoroidektomije.

Harmonic Scalpel® pretvara električnu energiju u ultrazvučne mehaničke vibracije visoke frekvencije (55 000 Hz) i na taj način vrši koagulaciju i presecanje tkiva. Aktivna oštrica makaza ovog aparata vibrira sa ekscurzijama od 50 do 100 mikrona u odnosu na pasivnu oštricu. Oštrijom ivicom makaza vrši se sečenje, a drugom, tupom, koagulacija tkiva. Ultrazvučna energija visoke frekvencije dovodi do cepanja vodonikovih veza u proteinima i na taj način do njihove denaturacije. Temperature koje se tom prilikom stvaraju su niže (oko 80°C), a samim tim i termičko oštećenje okolnog tkiva je minimalno [5]. Dubina oštećenja okolnog tkiva iznosi manje od 1,5 mm. Poređenja radi, dubina termičkog oštećenja kod upotrebe lasera iznosi oko 4 mm. Smatra se da je minimalno oštećenje okolnog tkiva, osnovni uzrok smanjenja postoperativnog bola kod pacijenata nakon HS hemoroidektomije.

Druga dobra odlika HS hemoroidektomije jeste dobra hemostaza. HS je pokazao mogućnost zbrinjavanja i većih krvnih sudova kao što je to slučaj u kolorektalnoj hirurgiji [12]. I u našem radu HS je pokazao dobre rezultate. Kod pacijenata kod kojih je urađena HS hemoroidektomija javilo se samo jedno postoperativno krvarenje, i ono je zbrinuto kratkotrajnom tamponadom. Tokom rada sa HS uočili smo da je za presecanje tkiva i dobru hemostazu potrebno strpljenje, jer ultrazvučne makaze HS aparata imaju sporiji režim rada. Smatramo da je potrebno izbegavati povlačenja tkiva prilikom presecanja. Ono dovodi do odsecanja tkiva a da pri tome hemostaza nije adekvatno napravljena.

and stage IV. Milligan-Morgan's concept of hemorrhoidectomy still represents the "golden standard" in the surgical treatment of hemorrhoidal disease [7]. Realizing that MM hemorrhoidectomy causes a significant level of postoperative pain, there have been numerous modifications of this procedure. Some included technical modifications, such as partial or total closure of the mucous membrane following excision of hemorrhoidal nodes, or internal lateral sphincterotomy. Advances in technology have led to the use of such devices as electrocauteries, dopplers, staplers and lasers [4,8,9].

Over the past few years we have witnessed publishing of several papers by various authors [10,11], which describe lower pain levels following HS hemorrhoidectomy. Learning from the experiences of those authors we have applied the same method at our clinic. Our five-year experience in treating hemorrhoidal disease using this method has confirmed lower levels of postoperative pain in relation to the MM procedure. Lower level of pain was statistically significant in the first week after surgery. A reduced incidence of urinary retention following HS procedure, although statistically not significant, also points to decreased pain intensity.

Pain following MM procedure can be explained by positioning the ligature onto the vascular root of the hemorrhoid, while electrocautery and laser procedures cause significant heat damage to the sensitive perihemorrhoid area. Reduction of this heat is considered to be the main reason for decreasing the level of pain after HS hemorrhoidectomy.

Harmonic Scalpel® transforms electricity into high frequency ultrasound mechanical vibrations (55000Hz), thus coagulating and cutting tissues. The active blade of scissors vibrates at 50 to 100 microns in relation to the passive blade. The sharper blade cuts tissues, while the other one, more blunt, does the coagulation. High frequency ultrasound energy causes destruction of hydrogen bonds within the proteins and also their denaturation. Temperature released during the procedure is lower (80 degrees C) and the heat damage of the surrounding tissues is minimal [5]. The extent of the surrounding tissue damage is less than 1.5 mm compared to 4 mm damage caused by the laser procedure. This reduction of damage in the surrounding tissues is considered to be the main cause of lower postoperative pain in HS hemorrhoidectomy.

Another positive aspect of HS hemorrhoidectomy is good hemostasis. HS has proved to be effective with larger blood vessels as exemplified by colorectal surgery [12]. HS has shown good results in our practice. Only one patient who underwent HS hemorrhoidectomy had postoperative hemorrhaging, which was treated with short term tamponade. The HS procedure requires patience for cutting tissues and for a good hemostasis, since the ultrasound HS scissors have a slower pace. We believe that it is important to avoid pulling the tissue during cutting. Pulling leads to cutting tissues without adequate hemostasis.

Zaključak

Harmonic Scalpel® hemoroidektomija nije bezbolna procedura, ali je stepen postoperativnog bola znatno manji od stepena bola nakon Milligan-Morganove hemoroidektomije. Broj komplikacija nakon *Harmonic Scalpel*® hemoroidektomija je manji iako statistički nesigifikantno.

Conclusion

Harmonic Scalpel® hemorrhoidectomy is not a painless procedure, but the level of postoperative pain is significantly lower after this procedure than after MM hemorrhoidectomy. The number of complications after *Harmonic Scalpel*® hemorrhoidectomy is lower, although statistically not significant.

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