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Comparing topical hydrocortisone cream with Hai's Perianal Support in managing symptomatic hemorrhoids in pregnancy: A preliminary trial

Soo Soo Lim[1], Chye Wah Yu[2] and Lin Da Aw[3]

[1]*KPJ Penang Specialist Hospital, Seberang Jaya, Penang,* [2]*Faculty of Allied Health Professions, AIMST University, Bedong, and* [3]*Reproductive Unit, Obstetrics and Gynecology Department, Hospital Sultanah Bahiyah, Alor Setar, Kedah, Malaysia*

Abstract

Aim: The prevalence of hemorrhoids among pregnant women is high in late pregnancy. This study was to evaluate the efficacy between drug treatment with Procort (topical hydrocortisone cream 1%) and mechanical treatment with a Hai's Perianal Support (HPS) toilet seat device in managing symptomatic hemorrhoids during the third trimester of pregnancy.

Methods: A prospective randomized controlled study was conducted on 23 pregnant women with gestation above the 28th week and presented with symptomatic hemorrhoids. Pre- and post-interventional assessment was carried out to obtain data on symptoms of pain, itching, swelling, discomfort and bleeding associated with hemorrhoids. The control group was treated with topical hydrocortisone cream 1% and the test group was provided and taught to use a HPS, a posterior perineal support toilet seat device (Colorec).

Results: The results showed improvement in symptoms of pain, swelling, bleeding, itching and discomfort in both the test and control groups. However, statistically significant differences were found on symptoms of pain, swelling and discomfort between the test and control groups. There was also a statistically significant difference in well-being and overall improvement between the test and control groups.

Conclusion: HPS has to a certain extent significantly reduced the symptoms of hemorrhoids in pregnancy and improved the well-being of pregnant women in comparison with topical treatment with hydrocortisone cream. However, more clinical trials need to be carried out to recomfirm the role of HPS in hemorrhoids in pregnancy.

Key words: hemorrhoids, posterior perineal support, pregnancy, topical hydrocortisone.

Introduction

Hemorrhoids have a serious impact on women's well-being. Despite their high occurrence, hemorrhoids tend to be considered as a normal phenomenon of pregnancy; combined with a general fear of using medications in pregnancy, there is inadequate management of this condition.

Prevalence of hemorrhoids in pregnancy varies in different localities. Hemorrhoids have been reported to occur in 38% of pregnant women,[1] and even up to 85% in some specific populations in late pregnancy.[2] Their treatment is usually via a medical approach with local drugs (corticoid and anesthetic cream), defecation regulation and analgesics.[3] Many women seek relief from their hemorrhoid symptoms by using one or more of the many anti-hemorrhoidal products that are available over the counter; none of which have been evaluated for safety in pregnancy.

Asymptomatic hemorrhoids are considered a normal part of the anatomical structure during pregnancy; however, excessive venous dilatations of the

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Reprint request to: Dr Chye Wah Yu, Faculty of Allied Health Professions, Semeling, Bedong, Kedah 08100, Malaysia.
Email: chyewah@gmail.com

hemorrhoidal plexus due to abnormal downward displacement of vascular anal cushions can lead to severe discomfort, bleeding and thrombosis, leading to painful ulcerations.[4,5] It is in this instance when most of the patients decide to seek treatment.

Pregnancy is a well-known risk factor for the development of both internal and external hemorrhoids.[6–8] Many conditions in pregnancy are associated with this increased risk of hemorrhoids: First is that the gravid uterus increases intra-abdominal pressure which compress the pelvic veins and the inferior vena cava, causing venous dilatation and engorgement of the hemorrhoidal plexus.[9,10] Pregnancy can predispose women to congestion of the anal cushion and symptomatic hemorrhoids.[10] Today, the theory of sliding anal canal lining is widely accepted, and this theory suggests that hemorrhoids develop when the supporting tissues of the anal cushions disintegrate or deteriorate.[10,11] Second is that the increased blood volume by up to 50% in the third trimester contributes to venous engorgement.[9,12] Third is the elevated levels of circulating progesterone[13] which can lead to venous dilation and result in swelling of the affected area; in addition, the relaxed gastric smooth muscle, which causes delayed gastric emptying, decreased gastroesophageal sphincter tone and decreased gut motility,[13] leads to constipation, which further aggravates hemorrhoids. Moreover, raised progesterone level relaxes and sags the pelvic floor, which causes an obstructive type of constipation.[14] Constipation in turn complicates to various anorectal problems including hemorrhoids. Oral iron supplements are also thought to cause constipation.[15] High parity also increased the risk of developing hemorrhoids. Prolonged labor with history of microsomia was also associated with a higher incidence of hemorrhoids.[16]

It is useful to classify hemorrhoids accordingly because the classification not only helps in selecting treatment, but also allows the comparison of therapeutic outcomes among them. Generally, hemorrhoids are classified into internal and external hemorrhoids. Internal hemorrhoids originate from the inferior hemorrhoidal venous plexus above the dentate line and covered by mucosa, while external hemorrhoids are dilated venules of this plexus and are covered with squamous epithelium.[10] For practical purposes, internal hemorrhoids are further classified using Goligher's classification which is based on the appearance and degree of prolapse: (i) first-degree hemorrhoids bleed but do not prolapse and are hidden inside the anal cushion and only visible with a proctoscope; (ii) second-degree hemorrhoids prolapse during defecation but spontaneously reduce after defecation; (iii) third-degree hemorrhoids prolapse on straining and can be reduced manually after defecation; and (iv) fourth-degree hemorrhoids remain prolapsed and cannot be reduced manually. The common sites of internal hemorrhoids are at the three major hemorrhoidal cushions to the right posterior, right anterior and left lateral position equivalent to the 3, 7 and 11 o'clock positions of the anal cushions.[10] Regardless of the stages of hemorrhoids, the difficult defecation and straining during defecation would worsen the condition.

Hemorrhoids are progressive in nature during the course of pregnancy, and many women experience significant impact on their quality of life with symptomatic hemorrhoids, especially during the third trimester of pregnancy. Symptoms manifested by patients may vary depending on the type of hemorrhoids. Many patients seek medical attention when experiencing bleeding, pain and itching. External hemorrhoids are associated with significant pain, severe discomfort, bleeding and itching, and sometimes thrombosis and strangulation.[3] Enlarged internal hemorrhoids are generally associated with soiling, bleeding, prolapse after defecation and pruritus ani in severe cases. However, due to lack of somatic sensory innervation, pain is not a common symptom.[3]

Treating hemorrhoids in pregnancy is not easy. There is a sense of fear of teratogenic effects of drugs in pregnancy. Hemorrhoids in pregnancy tend to be more severe and prolonged, but usually completely resolve soon after birth.[17] As hemorrhoids are expected to resolve spontaneously on their own, the condition is generally dismissed by many physicians and women have to endure the symptoms until delivery. Treatment of hemorrhoids in pregnancy is symptomatic in pregnancy regardless of the grades and types of hemorrhoids. For external hemorrhoids with thrombosis in pregnancy, local treatment with corticoids and anesthetics is recommended coupled with defecation regulation and paracetamol.[3] Non-steroidal anti-inflammatory drugs can be used only after delivery in the absence of breast-feeding.[3] Surgery is not the preferred choice in pregnancy because medical treatment is sufficient in most cases. Nevertheless, for non-pregnant patients, the use of surgery is required for most advanced stages. For instance, rubber band ligation and phlebotonic drugs are used to treat first- and second-degree hemorrhoids; mucopexy with or without mucosal resection or hemorrhoid artery

ligation is recommended for third-degree hemorrhoids; whereas Milligan–Morgan hemorrhoidectomy is the gold-standard treatment for fourth degree hemorrhoids.[18]

Topical treatment with cream or ointment containing anesthetics, steroids and anti-inflammatory agents provides short-term relief from pain, bleeding, swelling and discomfort. One of the topical medications used is hydrocortisone. It is a synthetic corticosteroid that is similar to cortisol. It is less potent than other corticosteroids and has widespread physiological effects such as carbohydrate, lipid and protein metabolism, immunosuppression and anti-inflammatory properties.[19] When used topically, general onset of action is seen within 7 days,[20] and is cleared quickly from the body, with a plasma clearance of 362 mL/min.[19] The primary function of hydrocortisone is decreasing inflammation and hence the pain, swelling and discomfort symptoms secondary to inflammation. The absorption through topical use is reported to range 3–7%.[21,22] Placental transfer is minimal.[22,23] Several studies have demonstrated the dose-dependent teratogenic effects of oral corticosteroid use; systemic glucocorticoids have consistently produced cleft palate in animal reproductive studies.[24] Four retrospective case–control studies have found an association with oral cleft.[25] In contrast, several prospective cohort studies have failed to show an association between exposure to corticosteroids in pregnancy and any major malformations.[26] None of the above risks for malformations and adverse fetal effects have thus far been associated with the topical use of corticosteroids.

Rectal bleeding, pain, pruritus or prolapse are nonspecific symptoms that accompany many anorectal conditions, including hemorrhoids. A thorough medical history as well as a physical examination is generally the most appropriate way to make a conclusive diagnosis, and to rule out more serious diseases such as proctitis, inflammatory bowel disease, anal cancer and colorectal tumors.[27,28] A thorough examination by a physician may include visual inspection of the rectum, digital rectal examination, and anoscopy or proctosigmoidoscopy. These procedures, though painless, are embarrassing and uncomfortable for most patients.

The aim of this study is to compare the efficacy between Procort (topical hydrocortisone cream 1%) and Hai's Perianal Support (HPS) a supplementary mechanical anococcygeal support device in relieving symptoms of pain, itching, bleeding, swelling and discomfort among pregnant women with hemorrhoids, and to further examine the impact on well-being and overall improvement in patients between the two treatment modalities.

Methods

This was a prospective randomized clinical trial conducted at Seberang Jaya General Hospital, a public tertiary hospital located in a northern state of Peninsular Malaysia. The selected patients were reviewed and pretreatment assessment was performed at the first appointment. A follow-up was performed after therapy which was scheduled at weeks 1, 2 and 3. The study was conducted from January 2012 to October 2012.

Pregnant women in their third trimester with symptomatic hemorrhoids were recruited at Obstetrics and Gynecology Clinic in this tertiary hospital. These patients were briefed on the research protocol, especially in regards to research topic, objectives, methods used and expected outcomes. They were informed about the risks and benefits of this study and they were also told that they had the liberty to participate or withdraw should they wish to do so at any point of time. Informed consent was obtained during the initial pretreatment assessment session. This trial was registered with the National Medical Research Registry and obtained ethical clearance from the Medical Research Ethic Committee, Ministry of Health, Malaysia.

Only consenting women in the third trimester of pregnancy (28th gestational week onwards) were recruited. Inclusion criteria were pregnant women with low-risk pregnancy with no evidence of complications, and who had been diagnosed with primary anorectal conditions that were not caused by a systemic disease such as portal hypertension. Exclusion criteria were women who had been exposed to known teratogens during pregnancy; pregnant women younger than 18 years old; women who used systemic corticosteroid medication; women with medical conditions and contraindications of hydrocortisone cream usage (e.g. anorectal abscess, fistula, tuberculosis, varicella, acute Herpes simplex or fungal infections); women who had allergy to hydrocortisone cream; and women with known intrauterine growth restriction (IUGR) or known chronic conditions associated with IUGR (e.g. systemic lupus erythematosus, placental insufficiency).

A clinically significant difference in the primary outcome, pain, is thought to be a minimum decrease of 2 points on a 10-point numerical rating scale. From a study employing a similar 10-point numerical scale,

with a power of 95% and an alpha error of 0.05, only 23 subjects were needed to achieve statistical significance. A formula for a two-sided test of 5%, namely, $m\,(\text{size per group}) = \frac{2c}{\delta^2} + 1$, was used for sample size calculation in this study as the primary outcome of interest was the mean difference in an outcome variable between two treatment groups.[29]

Consenting patients who met the inclusion criteria were randomized to Procort or HPS groups using computer-generated randomization. Diagnosis was confirmed by rectal examination. Upon recruitment, women were asked to complete the antenatal questionnaire. The second assessment, the postnatal questionnaire, was completed up to 1 month after delivery (Fig. 1).

Procort is a topical hydrocortisone cream 1% that was prescribed to patients in the control group. These patients were further instructed to apply it as a thin film of approximately 0.5 cm in diameter to affected areas twice daily till they were reviewed in the clinic after treatment at weeks 1, 2 and 3.

Hai Perianal Support is an innovative bowel aid employed in this trial. It incorporates a mechanical posterior anococcygeal support device attached to a standard toilet seat (Colorec) (Fig. 2). This patented bowel aid system is produced by Mecha-Medic Solution, a company from Penang, Malaysia. The Colorec bowel aid consists of a cover, seat and the patented additional protrusion from the rear portion of the toilet seat. To date, three clinical studies have been conducted using HPS in the management of chronic anal fissures and the results were mixed in regard to improvement of symptoms in patients with chronic anal fissure.[14,30,31] This study is the first using HPS in the management of hemorrhoids in pregnancy. In this trial, patients were taught how to use HPS by demonstration before the intervention and on the correct technique of positioning themselves while sitting on the device during defecation, which was reinforced at the follow-up at weeks 1, 2 and 3.

The Colorectal Evaluation of Clinical Therapeutics Scale (CORECTS), a six-item questionnaire, was completed by patients from the control and test groups prior to initiation of treatment, and after treatment at weeks 1, 2 and 3. This scale has been used to assess five major symptoms of hemorrhoid – pain, itching, swelling, bleeding and discomfort – each rated on a 0–10 scale, where 0 indicates no symptoms and 10 indicates worst possible symptoms.[32] It also accounts for quality of life with an 'impact on well-being score', which measures the impact of hemorrhoidal symptoms on well-being, and also ranges from 0 (no impact) to 10 (best possible impact). The CORECTS also assesses the total improvement in symptoms following treatment with an 'overall improvement' score, with a score of 0 indicating no improvement at all and 10 indicating maximal improvement comparable to the healthy state (Fig. 3).[32] The reliability of the CORECTS was validated in a study involving 209 pregnant women in Canada with symptoms associated with anorectal conditions and the results indicated that the CORECTS is a reliable and sensitive tool in evaluating the severity of symptoms associated with colorectal symptoms in pregnancy.[32]

Pain is the most common complaint in hemorrhoid sufferers, with the most impact on well-being. Hence, pain is taken as the primary outcome. The other hemorrhoidal symptoms – itching, bleeding, swelling and discomfort – as well as improvement in well-being and global improvement scores, were the secondary outcomes for the study.

Repeated measures ANOVA tests were used to evaluate any significant differences on primary and secondary outcomes between pregnant women on hydrocortisone cream and HPS for symptomatic hemorrhoids. An independent Student's *t*-test was used to compare the overall improvement between the test and control groups.

Results

There were a total of 23 patients with 11 on the treatment arm and 12 on the control arm. However, two patients defaulted treatment and dropped out of the study phase; thus, 10 patients used HPS toilet seat device and 11 patients on Procort 1%, with their age ranging 22–40 years. Of the patients, 9.5% were primigravida, while the rest were multigravida, while 61.9% reported having constipation with less than average bowel movement. All 21 patients completed all items in the CORECTS questionnaires during the initial pretreatment phase and in the last post-treatment phase at week 3.

The means of symptoms of pain, itching, swelling, bleeding and discomfort showed a decreasing trend after intervention from week 1 to week 3 in test and control groups, whereas the means for well-being score showed an increasing trend (Table 1). The control group experienced pain reduction from 22.12% to 37.78% from week 1 to week 3, while the test group showed pain reduction from 19.15% to 85.11% from

(i) Antenatal Questionnaire Case no:

Name:
I.C:
Race:
Phone no:
Age:
Ht: Wt:
G_____P____A____Ectopic____Molar____Gestation_____ weeks
(EDD_____)
Obstetric History

No	SVD/LSCS	BW

Medical History:
- ☐ Diabetic
- ☐ Hypertension
- ☐ Anaemia
- ☐ Others:……

Surgical History:
Allergy:
Education: primary / secondary/ diploma/ degree/ master
Occupation:
Anorectal symptoms:
Bower movement:_____/week
- ☐ Anal pain
- ☐ Itching
- ☐ Swelling
- ☐ PR bleed

Previous treatment:

(ii) Postnatal Questionnaire

Gestation at delivery:
Mode of delivery:
- ☐ LSCS: Indication:
- ☐ SVD: Episiotomy/ tear: 1st degree/ 2nd degree/ 3rd degree

Birth Weight:
Gender:
AS:
Wound breakdown: Y/N

	1st week	2nd week	3rd week	4th week
Stress Incontinence				

Figure 1 Antenatal and postnatal questionnaire for clinical assessment. A, abortion; AS, Apgar score; BW, bodyweight; EDD, expected date of delivery; G, gravida; I.C., identity card; LSCS, lower section cesarean section; P, para; PR, per rectum; SVD, spontaneous vaginal delivery.

Figure 2 Hai's Perianal Support (HPS) toilet seat device (Colorec).

How much pain do you experience?
0 1 2 3 4 5 6 7 8 9 10

How much itching do you experience?
0 1 2 3 4 5 6 7 8 9 10

How much swelling do you experience?
0 1 2 3 4 5 6 7 8 9 10

How much bleeding do you experience?
0 1 2 3 4 5 6 7 8 9 10

How much discomfort do you experience?
0 1 2 3 4 5 6 7 8 9 10

How much impact does you condition have on your wellbeing?
0 1 2 3 4 5 6 7 8 9 10

How do you rate the overall improvement after treatment?
[Post treatment]
0 1 2 3 4 5 6 7 8 9 10

*Pretreatment/ Post treatment 1 week/ 2 weeks/ 3 weeks

Figure 3 The Colorectal Evaluation of Clinical Therapeutics Scale (CORECTS).

week 1 to week 3. Hence, pain in the test group was reduced by a greater percentage (85.11% – 19.15% = 65.96%) when compared to the control group (37.78% – 22.12% = 15.66%).

In terms of itching symptom, the control group did not experience a reduction in itching from week 1 (0%) to week 2 (0%), but pain was reduced in week 3 at 54.55%. On the other hand, the test group experienced a reduction in itching from 33.33% in week 1, 66.67% in week 2, to 100% in week 3. Therefore, the test group seemed to experience a greater reduction in itching (100% – 33.33% = 66.67%) than the control group (54.55% – 0% = 54.55%).

In terms of the symptom of swelling, the control group experienced reduction from 16.07% in week 1, 17.86% in week 2, to 26.79% in week 3. The test group experienced reduced swelling from 37.84% in week 1, 56.76% in week 2, to 75.68% in week 3. Thus, the test group experienced a greater percentage of reduced swelling (75.68% – 37.84% = 37.84%) than the control group (26.79% – 16.07% = 10.72%).

Bleeding was not relieved in the control group at all from week 1 to week 3, while the test group experienced reduced bleeding tremendously from 64.71% in week 1, 94.12% in week 2, to 100% in week 3. The test group seemed to experience a greater reduction in bleeding (100% – 64.71% = 35.29%) than the control group (0%).

In terms of the symptom of discomfort, the control group experienced reduced discomfort from 16.67% in week 1, 18.52% in week 2, to 24.07% in week 3, whereas the test group experienced a greater reduction of discomfort from 48.15% in week 1, 66.67% in week 2, to 81.48% in week 3. Thus, the test group experienced a greater reduction in discomfort (81.48% – 48.15% = 33.33%) than the control group (24.07% – 16.67% = 7.4%).

In terms of improvement of well-being of pregnant women, the well-being score reported for the control group increased from 10.71% in week 1, 14.29% in week 2, to 19.64% in week 3, whilst the well-being score for the test group increased from 63.16% in week 1, 84.21% in week 2, to 115.79% in week 3. Thus, the well-being score for the test group increased more in percentage (115.79% – 63.16% = 52.63%) than the control group (19.64% – 10.71% = 8.93%).

Repeated measures ANOVA results revealed that there were significant differences between the test and control group in pain (F [3, 51] = 8.509, $P < 0.001$), swelling (F [1.873, 33.709] = 5.367, $P = 0.011$) and discomfort (F [1.852, 14.817] = 25.120, $P < 0.001$). No statistically significant differences were found between the test and control group in itching (F [1.217, 21.906] = 0.466, $P = 0.549$) and bleeding (F [1.519, 27.334] = 3.091, $P = 0.074$). Looking at the impact of

Table 1 Distribution of primary and secondary outcomes between test and control group

Symptoms	Group	Time (weeks)	Mean	SE	95% CI Lower	95% CI Upper	*P*
Pain	Test	Pre	5.875	0.907	3.952	7.788	0.000**
		T1	4.750	0.703	3.258	6.232	
		T2	2.250	0.613	0.956	3.544	
		T3	0.875	0.684	–0.568	2.318	
	Control	Pre	4.091	0.773	2.460	5.722	
		T1	3.182	0.599	1.918	4.446	
		T2	2.818	0.523	1.715	3.921	
		T3	2.545	0.583	1.315	3.776	
Itching	Test	T1	1.000	0.694	–0.458	2.458	0.549
		T2	0.667	0.667	–0.734	2.067	
		T3	0.333	0.598	–0.924	1.590	
		T4	0.000	0.375	–0.787	0.787	
	Control	Pre	1.000	0.628	–0.319	2.319	
		T1	1.000	0.603	–0.267	2.267	
		T2	1.000	0.541	–0.137	2.137	
		T3	0.455	0.339	–0.257	1.166	
Swelling	Test	Pre	4.111	0.909	2.202	6.020	0.011*
		T1	2.556	0.938	0.586	4.525	
		T2	1.778	0.934	–0.184	3.739	
		T3	1.000	0.868	–0.825	2.825	
	Control	Pre	5.091	0.822	3.364	6.818	
		T1	4.273	0.848	2.491	6.054	
		T2	4.182	0.844	2.408	5.956	
		T3	3.727	0.786	2.077	5.378	
Bleeding	Test	Pre	1.889	0.683	0.454	3.324	0.074
		T1	0.667	0.581	–0.554	1.888	
		T2	0.111	0.382	–0.691	0.913	
		T3	0.000	0.375	–0.787	0.787	
	Control	Pre	0.455	0.618	–0.844	1.753	
		T1	0.455	0.526	–0.650	1.559	
		T2	0.455	0.345	–0.271	1.180	
		T3	0.455	0.339	–0.257	1.166	
Discomfort	Test	Pre	6.000	0.965	3.972	8.028	0.000**
		T1	3.111	0.916	1.188	5.035	
		T2	2.000	0.889	0.133	3.867	
		T3	1.111	0.835	–0.644	2.866	
	Control	Pre	4.909	0.873	3.075	6.743	
		T1	4.091	0.828	2.351	5.831	
		T2	4.000	0.804	2.311	5.689	
		T3	3.727	0.756	2.140	5.315	
Well-being	Test	Pre	4.222	1.055	2.005	6.440	0.000**
		T1	6.889	0.960	4.871	8.907	
		T2	7.778	0.893	5.902	9.654	
		T3	9.111	0.838	7.350	10.872	
	Control	Pre	5.091	0.955	3.085	7.097	
		T1	5.636	0.869	3.811	7.462	
		T2	5.818	0.808	4.121	7.515	
		T3	6.091	0.758	4.498	7.684	

*$P < 0.05$, **$P < 0.01$. CI, confidence interval; SE, standard error; T, time point.

intervention in terms of well-being score, repeated measures ANOVA results revealed a statistically significant difference in well-being between the test and control group (F [1.894, 34.086] = 14.944, $P < 0.001$).

Independent Student's t-test results showed a significant difference in overall improvement between the two treatment modalities (t [12 510] = 2.270, $P < 0.05$). The box plot distribution of the overall improvement

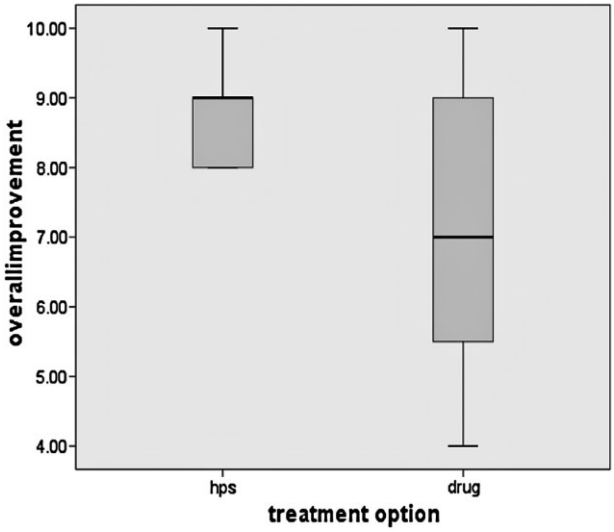

Figure 4 Box plot for overall improvement after treatment between Hai's Perianal Support (HPS) and drug (Procort 1%).

score between the test and control group showed that the test group experienced a higher median improvement score as compared to the control group (Fig. 4).

Discussion

Pregnancy predisposes women to hemorrhoids, causing downward displacement of the anal cushions. Many pregnant women seek medical help to avoid serious complications of inflammation, thrombosis and prolapse. The five cardinal symptoms of hemorrhoids in pregnant women generally improved progressively after treatment with both types of modalities in this study. Overall, the test group showed more significant reduction in pain, swelling and discomfort than the control group. In terms of impact on well-being, the test group reported a more significant impact than the control group. Symptoms of bleeding and itching were not significantly different between the groups, however, there was a marked change in relief of pain and itching before and after HPS intervention.

For the measure of overall improvement of pregnant women, the mean overall improvement score of patients in the test group (8.67) was not very large in comparison with patients in the control group (7.09), but there was a statistically significant difference in overall improvement between both groups. It is arguable that patients using HPS had a greater percentage reduction in symptoms of pain, itching, swelling, bleeding and discomfort in comparison with patients on Procort 1% and this contributed to a better overall improvement score.

The statistically significant results of improvement in symptoms of pain and discomfort in this study are consistent with an earlier non-randomized prospective study by Tan *et al*.[14] on use of HPS to provide perineal support during defecation for patients with chronic anal fissures.[14] In terms of overall improvement of patients, a randomized control trial by Chen *et al*.,[30] and a prospective non-randomized control trial by Gee *et al*.,[31] that used HPS in the treatment of chronic anal fissures did demonstrate improvement, but the results were insignificant. However, the finding of this study was quite encouraging for the use of HPS in the managemnt of hemorrhoids in pregnancy. The treatment of hemorrhoids during pregenacy presents a dilemma for doctors and health-care providers in choosing the best option that will not jeopaedize mother and fetal health. Oral medications can be useful but the risk to pregancy has not been established. Topical treatment with hydrocortisone 1% or suppositories that contain local anesthetics, mild astringents or steroids are thought to be safe treatments, but the risk of systemic and tetrogenic effects on the fetus have so far not been confirmed in many clinical trials.

Pregnant women are advised to adjust their dietary habits by increasing intake of fibers and oral fluid, to undergo training in healthy toilet habits, participate in exercise, maintain anal hygiene, and avoid constipation and straining during defecation as these measures may improve the symptoms experienced by the patients in this study. The correct technique of using HPS was reinforced in patients, including adjusting their position and accustoming themselves to this position while sitting on the toilet seat, to assist better outcome when using HPS. The pregnant women using HPS felt safer and more comfortable as this mechanical device did not give rise to any side-effect or discomfort as compared with oral medication or surgical procedures.

It is believed that HPS, which acts as bowel aid by providing mechanical support of the anococcygeal region, assists in easy and effective defecaction and prevents constipation due to obstructive defecation.[14] With easier defecation, less straining is needed and hemorrhoidal vein engorgement is prevented, resulting in symptomatic improvement of swelling, itching and discomfort associated with hemorrhoids. In addition, HPS helps to prevent backward overstretching of the anus which in long-term may lead to an anal

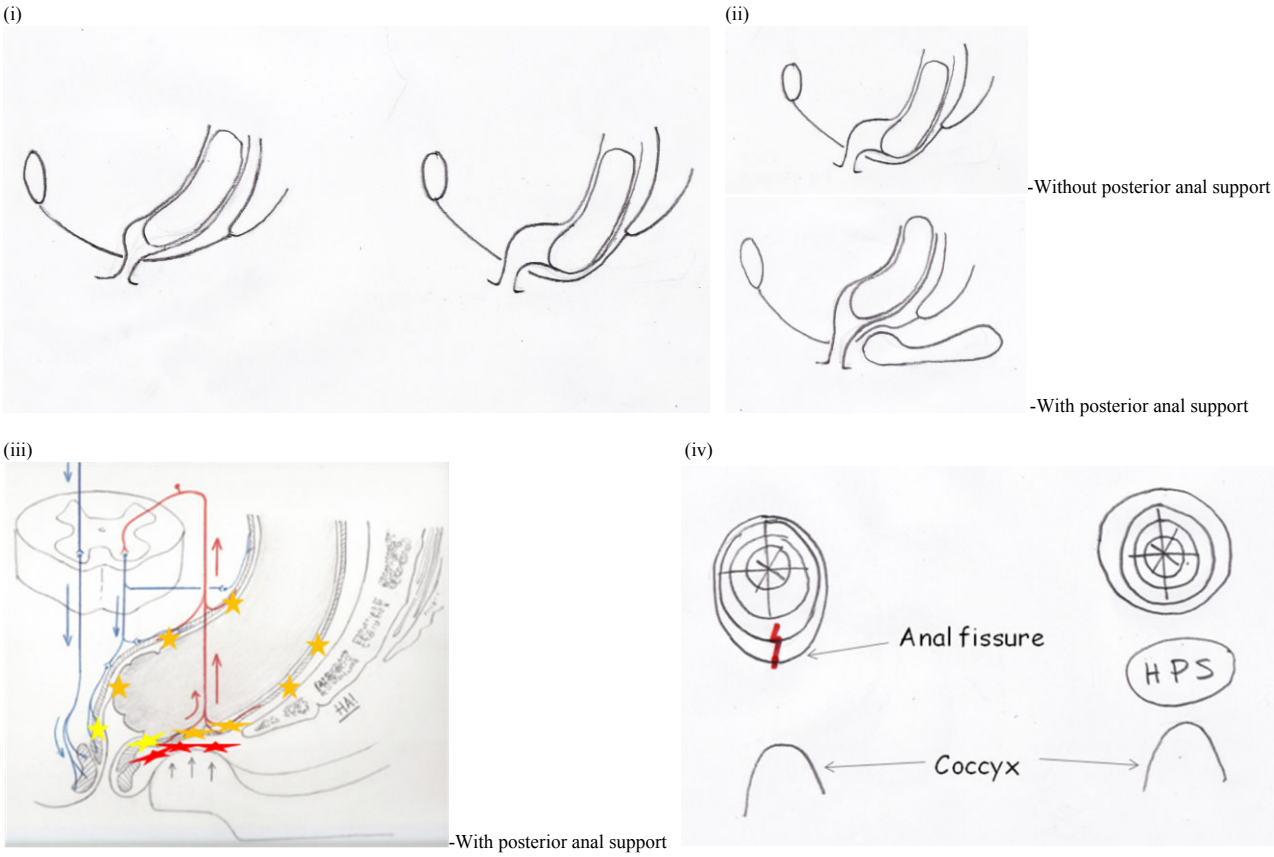

Figure 5 Mechanism of Hai's Perianal Support (HPS): (i) formation of obstructive defecation; (ii) corrected obstructive defecation; (iii) enhanced reflex of defecation; and (iv) prevention of backward overstretching of the anus.

fissure.[14] Without overstretching of the anal mucosa, pain and anal bleeding associated with anal fissures, which are very commonly associated with hemorrhoids, will be ameliorated.[31] Because the intervention of the mechanism of action is physical, the corrective effect is instant and the results of this study did demonstrate the improvement in three of the five cardinal symptoms of hemorrhoids. The small sample in this study might have limited the possible detection of any statistical difference in other two symptoms. Exiguous studies conducted on HPS in the past revealed inconclusive findings on the efficacy of HPS in the manageemnt of anorectal diseases.[14,30,31] This study will serve as a preliminary trial and open the way for more studies on posterior perineal support devices in the management of hemorrhoids in pregnant and non-pregnant patients.

Both treatment modalities were effective in relieving symptoms of hemorrhoids for pregnant women during late pregnancy in this pilot trial. However, HPS showed a better improvement score in terms of pain, swelling and discomfort. The patients also experienced an increase in well-being score and this may ensure that pregnant women will be able to go through a comfortable and uneventful delivery without the distress of hemorrhoids. To validate the results of this trial, it was suggested that a larger randomized control trial needs to be conducted to recomfirm the novel role of HPS in the treatment of hemorrhoids for pregnant women. Because it is only an external support, it carries no reproductive risk, making it a very promising solution for pregnant women with hemorrhoids where current medical practice has very limited options to offer.

No matter what definition of hemorrhoids a person believes, there is common ground in the belief that straining in defecation worsens hemorrhoids and predisposes subjects to serious symptoms and complications. HPS aids in the process of defecation by preventing sagging and bending of the anal passage

during defecation. In other word, it smoothens the passage and also enhances the reflex of defecation (Fig. 5). With that, it minimizes the need of straining during defecation, which woud benefit the hemorrhoids and prevent constipation.

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Disclosure

None of the authors has anything to disclose.

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