Comparison on the Efficacy of Dexpanthenol in Sea Water and Saline in Postoperative Endoscopic Sinus Surgery

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Objective: To compare the efficacy of dexpanthenol spray and saline irrigation in the postoperative care of sinusitis patients following endoscopic sinus surgery (ESS).

Material and Method: One hundred twenty eight sinusitis patients undergoing ESS were randomly allocated to receive dexpanthenol spray (Mar plus) or saline irrigation twice a day for 4 weeks after the operation. Total nasal symptom score, crusting, infection, compliance, and patient satisfaction were evaluated at 1, 2-3, 4-6, and 12 weeks. Mucociliary clearance was assessed with the saccharin test before ESS and at the last visit. One hundred ten patients remained at the present study termination. Chi-square test and Mann-Whitney U test were employed.

Results: Total nasal symptom score, mucociliary clearance, and infection improved in both groups after the operation. The dexpanthenol group resulted in a better mucociliary clearance than saline irrigation (9.93 ± 6.04 vs. 12.38 ± 9.32 min, p = 0.43). Saline irrigation resulted in a greater reduction of post nasal drip than dexpanthenol at the first visit (74% vs. 87%, p = 0.04). Compliance and patient satisfaction were comparable.

Conclusion: The efficacy of dexpanthenol was comparable to nasal saline irrigation in the postoperative care of sinusitis patients following endoscopic sinus surgery. Dexpanthenol is an alternative treatment, which may be useful in young children and complicated cases.

Keywords: Chronic sinusitis, Nasal irrigation, Sea water

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Nasal saline irrigation has been used in the treatment of patients with allergic rhinitis, chronic rhinosinusitis, and postoperative endoscopic sinus surgery. Isotonic saline nasal washing is one of the oldest methods used, because of its cheap and easy preparation. This procedure is safe in both adults and children and has no serious adverse effects. A high volume, low pressure isotonic saline rinsing of the nose and paranasal sinus is the preferred technique for cleansing the surgical cavity and improving wound healing. Suggested mechanisms are improving the mucociliary function of respiratory mucosa, decreasing mucosal edema, clearing static secretion, rinsing infective debris, removing the source of allergen and minimizing crusting, which may obstruct normal sinonasal drainage or lead to adhesions.

Dexpanthenol in sea water nasal spray is an isotonic solution. Dexpanthenol is an analog of pantothenic acid, which promotes wound healing. In an atrophic rhinitis study, it improved patients’ symptoms by repairing damaged mucosa. However, dexpanthenol spray has never been evaluated in the postoperative care of patients with rhinosinusitis.

Objective

To compare the efficacy of dexpanthenol in sea water nasal application (Mar plus) and normal saline irrigation in postoperative endoscopic sinus surgery patients. The present study protocol was approved by the ethical committee of Maharaj Nakorn Chiang Mai Hospital.
Material and Method

A prospective study was conducted in all postoperative endoscopic sinus surgery patients for rhinosinusitis at Maharaj Nakorn Chiang Mai Hospital, between July 2004 and December 2005. The exclusion criteria were malignant or granulomatous etiology and unwilling patients. The patients included in the present study were randomized into two groups, the first group received Dexpanthenol in sea water nasal spray 2 puffs per nostril, twice a day. The second group received normal saline nasal irrigation twice a day. The treatment was applied from the first postoperative day and continued for one month. Other postoperative care, such as topical steroid, antibiotics, and cleaning were applied in the same way.

All patients were evaluated according to the lists below.

1. Subjective assessments:
   Total nasal symptom score (TNSS) were obstruction, rhinorrhea, itching, sneezing, and post nasal drip (0 = symptom free, 1 = mild, 2 = moderate, 3 = severe symptom)

2. Objective assessments:
   - Crust: (0 = no crust, 1 = small crust confined to the ethmoid cavity, 2 = crust extended to the middle meatus, 3 = crust below the middle meatus)
   - Mucociliary clearance: saccharin test (SCT)
   - Secretion from antral irrigation in the first and second visit: (0 = clear, 1 = blood clot, 2 = mucoid secretion, 3 = mucopurulent secretion)

3. Other assessments:
   Cost, time, satisfaction, and compliance

The patients were evaluated at the 1st, 2nd or 3rd, 4th or 6th, and 12th week postoperatively by the study investigators.

Statistical analysis

Parameters were analyzed by the Mann Whitney U test, independent t-test, and Chi-square test with SPSS version 11.

Results

One hundred and twenty eight patients were enrolled in the present study, but only 110 patients had completed follow up. The demographic data of the two groups is summarized in Table 1. The only significant difference was the normal saline group had more nasal polyp than the Dexpanthenol in sea water group.

Total nasal symptom score (TNSS)

From the first visit, ‘symptom free’ subjects in the Dexpanthenol group was 38.1%, and improved to 58.6% in the fourth visit. While in the saline group, 29.7% had no symptoms in the first week, then 53.8% in the fourth visit. (Table 2) All symptoms were mild and there was no significant difference between visit 1 and 4. Common symptoms that remained were obstruction and rhinorrhea, while a mean symptom of TNSS in the saline group was 0.6-1.02, and 0.83-1.16 in the Dexpanthenol group.

The post nasal drips in both groups were markedly decreased from the preoperative visit. The saline group had a better TNSS than the Dexpanthenol group only in the first visit (p = 0.04). There were no other statistically significant differences (Table 3).

Antral irrigation

At the first post operative visit, endoscopic irrigation showed no secretion in 59.6% of the Dexpanthenol group and 47.6% of the saline group.

### Table 1. The baseline characteristics of sinusitis patients

<table>
<thead>
<tr>
<th></th>
<th>Dexpanthenol group (64 patients)</th>
<th>NSS group (64 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ± SD (range)</td>
<td>40.5 ± 15.7 (9-92)</td>
<td>36.0 ± 18.0 (8-87)</td>
</tr>
<tr>
<td>Children : adult</td>
<td>6:58</td>
<td>9:55</td>
</tr>
<tr>
<td>Male : female</td>
<td>34:30</td>
<td>29:35</td>
</tr>
<tr>
<td>Allergy test (% positive)</td>
<td>65.6</td>
<td>52.3</td>
</tr>
<tr>
<td>Chronic rhinosinusitis C NP*</td>
<td>20</td>
<td>34</td>
</tr>
<tr>
<td>Chronic rhinosinusitis*</td>
<td>41</td>
<td>29</td>
</tr>
<tr>
<td>Complicated acute sinusitis</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

* Chi-square test; p < 0.05
NP: nasal polyp
NSS = normal saline sinus
statistically significant difference between the two groups. The infection rate in both groups was 2.9-3.7%, which could be due to remaining inflammation from chronic sinus disease.

Crust formation (Table 4)
At the first visit, 70 to 80% of both groups had crust in the nasal cavity. There was no crust found in 19.3% of the dexpanthenol and 26% of the saline group. At the second visit, the saline group had significantly less crust score than the dexpanthenol group (Mann Whitney U test \( p = 0.03 \)).

At the third visit, most of the patients in both groups had no crust (90.3%, 96.2%).
There was no crust found in either group, at the last visit.

The saccharin test (SCT)
Preoperative saccharin transport time in both groups was no different from the mean SCT in the normal population. The mean SCT in the Dexpanthenol group was \( 13.46 \pm 10 \) min., while it was \( 13.08 \pm 9.9 \) min in the saline group.

At visit 4, postoperative, the mean SCT in the Dexpanthenol group was \( 9.93 \pm 6.04 \) min, and \( 12.38 \pm 9.32 \) min in the saline group (t-test \( p = 0.43 \)). None of the Dexpanthenol group had delayed SCT (more than 30 min.), but three cases had it (31, 35 and 35 min) in the saline group.

Table 2. The total nasal symptom score (TNSS) in each visit postoperative

<table>
<thead>
<tr>
<th>TNSS</th>
<th>Dexpanthenol group</th>
<th>NSS group</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>0 24 (38.1%)</td>
<td>19 (29.7%)</td>
<td>0.84</td>
</tr>
<tr>
<td></td>
<td>1 38 (60.3%)</td>
<td>44 (68.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 1 (1.6%)</td>
<td>1 (1.6%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Visit 2</td>
<td>0 33 (53.2%)</td>
<td>27 (44.5%)</td>
<td>0.56</td>
</tr>
<tr>
<td></td>
<td>1 29 (46.8%)</td>
<td>38 (54.5%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Visit 3</td>
<td>0 33 (56.9%)</td>
<td>25 (49%)</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>1 25 (43.1%)</td>
<td>27 (52%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Visit 4</td>
<td>0 34 (58.6%)</td>
<td>28 (53.8%)</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>1 23 (39.7%)</td>
<td>23 (44.2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 1 (1.7%)</td>
<td>1 (1.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* Mann Whitney U test
0 = no symptom, 1 = mild (TNSS 1-4), 2 = moderate (TNSS 5-8), 3 = severe (TNSS 9-12)

Table 3. Post nasal drip symptom score

<table>
<thead>
<tr>
<th>PND</th>
<th>Dexpanthenol group</th>
<th>NSS group</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>0 8 (12.9%)</td>
<td>17 (26%)</td>
<td>0.04**</td>
</tr>
<tr>
<td></td>
<td>1 44 (71.7%)</td>
<td>41 (63%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 6 (9.7%)</td>
<td>5 (7.2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 4 (6.5%)</td>
<td>1 (1.6%)</td>
<td></td>
</tr>
<tr>
<td>Visit 2</td>
<td>0 19 (30.6%)</td>
<td>25 (41.7%)</td>
<td>0.75</td>
</tr>
<tr>
<td></td>
<td>1 42 (67.7%)</td>
<td>30 (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 1 (1.6%)</td>
<td>5 (8.3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Visit 3</td>
<td>0 25 (43.1%)</td>
<td>24 (46.2%)</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td>1 27 (46.6%)</td>
<td>21 (40.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 5 (8.6%)</td>
<td>6 (11.5%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 1 (1.7%)</td>
<td>1 (1.9%)</td>
<td></td>
</tr>
<tr>
<td>Visit 4</td>
<td>0 27 (46.6%)</td>
<td>24 (46.1%)</td>
<td>0.48</td>
</tr>
<tr>
<td></td>
<td>1 26 (44.8%)</td>
<td>27 (52%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 5 (8.6%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

* Mann Whitney U test
** Statistically significance
0 = no symptom, 1 = mild symptom, 2 = moderate symptom, 3 = severe symptom

At the second visit, 80% of both groups showed no secretion. Other findings were blood clot, mucoid and mucopurulent secretion, which had no statistically significant difference between the two groups. The infection rate in both groups was 2.9-3.7%, which could be due to remaining inflammation from chronic sinus disease.

Crust formation (Table 4)
At the first visit, 70 to 80% of both groups had crust in the nasal cavity. There was no crust found in 19.3% of the dexpanthenol and 26% of the saline group. At the second visit, the saline group had significantly less crust score than the dexpanthenol group (Mann Whitney U test \( p = 0.03 \)).

At the third visit, most of the patients in both groups had no crust (90.3%, 96.2%).
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The saccharin test (SCT)
Preoperative saccharin transport time in both groups was no different from the mean SCT in the normal population. The mean SCT in the Dexpanthenol group was \( 13.46 \pm 10 \) min., while it was \( 13.08 \pm 9.9 \) min in the saline group.

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Table 4. The crust score

<table>
<thead>
<tr>
<th>Crust</th>
<th>Dexpanthenol group</th>
<th>NSS group</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>0 22 (19.3%)</td>
<td>27 (26%)</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>1 20 (17.5%)</td>
<td>27 (26%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 50 (43.9%)</td>
<td>28 (24.6%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 22 (19.3%)</td>
<td>22 (21.2%)</td>
<td></td>
</tr>
<tr>
<td>Visit 2</td>
<td>0 59 (51.8%)</td>
<td>70 (67.3%)</td>
<td>0.03**</td>
</tr>
<tr>
<td></td>
<td>1 29 (25.4%)</td>
<td>20 (19.2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 22 (19.3%)</td>
<td>11 (10.6%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 4 (3.5%)</td>
<td>3 (2.9%)</td>
<td></td>
</tr>
<tr>
<td>Visit 3</td>
<td>0 103 (90.3%)</td>
<td>100 (96.2%)</td>
<td>0.49</td>
</tr>
<tr>
<td></td>
<td>1 10 (8.8%)</td>
<td>2 (1.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 1 (0.9%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 0</td>
<td>2 (1.9%)</td>
<td></td>
</tr>
</tbody>
</table>

* Mann Whitney U test
** Statistically significance
0 = no crust, 1 = crust beyond middle meatus, 2 = crust at middle meatus, 3 = crust below middle meatus
The mean SCT in the Dexpanthenol group was less than in the saline group for chronic rhinosinusitis with nasal polyp (Table 5).

Both groups had 100% compliance and good patient satisfaction. The mean time used in the Dexpanthenol group was 1 minute per day compared to 11 minutes in the saline group. The cost of both groups was not much different (420 baht for saline, 344 baht for the dexpanthenol group).

Discussion

Postoperative care following endoscopic sinus surgery was more important than the surgery itself(5). There were two methods of postoperative cleansing, the first being suction under endoscope controlled by the surgeon(8-10). The second was nasal and paranasal sinus rinsing / washing or douching by the patients(8-11). Nowadays, many surgeons recommend weekly suction cleansing, starting one week after the operation to remove blood clot, fibrin, adhesion and crust, followed by nasal irrigation. Nasal saline irrigation also improves self-management of sinus symptoms(12).

Hypertonic saline was also recommended by various authors(13,14) because of the mucolytic property, although there was the drawback of pain from substance P release and glandular secretion by stimulation of nociceptive receptors(14).

In the present study, the saline group had more patients with nasal polyp. This might have resulted from the unconcealed randomization and could have made this group more disease severity. However, all patients had satisfactory wound healing in 2-3 weeks, although postnasal drip and crust were more prevalent in the Dexpanthenol group. This could be caused by technique application, as the copious saline flow could remove thick secretion and crust better.

Meta-analysis of the SCT in healthy controls was 14.7 ± 8.2 min (mean ± SD)(15). In Thailand, the mean normal SCT was 12 min(16). In the study of Sakakura, the mean SCT in an adult population (aged 15-59 years) was 13.7 ± 8.9 min(17). The mucociliary clearance was delayed in the population aged over 60 years, but 70% of the older population (> 60 yrs) still had normal mucociliary clearance. However, in chronic sinusitis, the mean SCT was prolonged (43.1 ± 18.2 min)(18,19). This was related to or caused by factors other than the rheologic properties of the mucus(20).

In the present study, both groups had a mean SCT within the normal range, which might be from topical nasal steroid usage that could improve mucociliary clearance(21). After the operation, both groups had even better mucociliary clearance.

The authors demonstrated that the efficacy of Dexpanthenol in sea water nasal spray was nearly as good as saline irrigation when comparing symptoms, crust, post nasal drip, sinus irrigation and the saccharin test in one month. Its application would be useful in small children and debilitated patients whose nasal irrigation is in difficulty.

Conclusion

The efficacy of Dexpanthenol in sea water nasal spray was almost comparable to the saline irrigation. Both methods were safe and satisfactory for postoperative patients. The Dexpanthenol group had more post nasal drip and crust in the first two weeks than the saline group, but the former consumed less time. The Dexpanthenol in sea water nasal spray was convenient for young children and complicated sinusitis patients, who could not clean their nose by irrigating themselves. Therefore, it is one of the choices for these groups of patients.

Conflict of interests

Dexpanthenol in sea water was sponsored by STADA Asiatic Co. Ltd.

<table>
<thead>
<tr>
<th>Table 5. Mean SCT preoperative and 4th visit, divided into a subgroup of chronic rhinosinusitis (CRS) with or without nasal polyp (NP)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SCT (mean)</strong></td>
</tr>
<tr>
<td>CRS/NP</td>
</tr>
<tr>
<td>Preoperative</td>
</tr>
<tr>
<td>Postoperative 4th visit</td>
</tr>
<tr>
<td>Mean improve SCT</td>
</tr>
</tbody>
</table>

* = 2 cases had SCT > 30 minutes
** = 1 cases had SCT > 30 minutes
References


การศึกษาเปรียบเทียบประสิทธิภาพของการพ่นจมูกด้วยน้ำทะเลผสม dexpanthenol และการล้างช่องจมูกด้วยน้ำเกลือในผู้ป่วยไซนัสอักเสบที่ได้รับการผ่าตัดด้วยการส่องกล้อง

สุปราณี ฟูอนันต์, สายสวาท ไชยเศรษฐ, กรณีการ์ รุ่งโรจน์วัฒนศิริ

วัตถุประสงค์: เพื่อเปรียบเทียบประสิทธิภาพของการพ่นจมูกด้วยน้ำทะเลผสม dexpanthenol และการล้างช่องจมูกด้วยน้ำเกลือ

วัสดุและวิธีการ: ศึกษาผู้ป่วยหลังการผ่าตัดในศูนย์พยาบาลปัญญาบัณฑิต 110 ราย แบ่งเป็น 2 กลุ่ม โดยกลุ่มที่ 1 ใช้น้ำทะเลผสม dexpanthenol (Mar plus) พ่นในช่องจมูก 2 ครั้งต่อข้าง วันละ 2 เวลา กลุ่มที่ 2 ใช้น้ำเกลือล้างจมูก ข้างละ 100 ลูกบาศก์เซนติเมตร วันละ 2 เวลา นาน 4 สัปดาห์ ติดตามผลในสัปดาห์ที่ 1, 2-3, 4-6 และสัปดาห์ที่ 12 ประเมินผลอาการทางจมูก โดยการทำการส่องกล้อง การทำงานของเซลล์ขน-กวัด และการประเมิน saccharin test โดยใช้ saccharin เวลาที่ใช้ ความพึงพอใจ และราคา สถิติที่ใช้วัด Chi-square test, Mann Whitney U test

ผลการศึกษา: พบว่าไม่มีความแตกต่างกันในอาการและอาการแสดง saccharin test ความพึงพอใจ และราคาของผู้ป่วยใน 2 กลุ่มที่ศึกษา ยกเว้น ความดันของ saccharin test ในกลุ่มน้ำทะเลผสม dexpanthenol ลดลงมากกว่ากลุ่มน้ำเกลือล้างจมูก แต่ไม่ได้ความแตกต่างอย่างมีนัยสำคัญทางสถิติ (9.93 ± 6.04 และ 12.38 ± 9.32 นาที, p = 0.43) อาการสมหะหลอดลดลงในกลุ่มน้ำทะเลผสม dexpanthenol เหตุเพราะในสัปดาห์แรกมีนัยสำคัญ (74% และ 87%, p = 0.04)

สรุป: น้ำทะเลผสม dexpanthenol และน้ำเกลือล้างจมูก มีผลไม่ต่างกันแต่อาการทางมดแก้วมีนัยสำคัญเกินกว่ากลุ่มน้ำทะเลผสม dexpanthenol ซึ่งมีประโยชน์ในผู้ป่วยที่ไม่สามารถล้างช่องจมูกเอง หลังจากการผ่าตัด เช่น ผู้ป่วยเด็ก ผู้ป่วยที่ช่วยเหลือตนเองได้ยาก เป็นต้น