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# Arnica Montana and Blood Loss, Surgical Field Bleeding and Operative Time in Endoscopic Sinus Surgery: A Randomized-Controlled Trial

## ABSTRACT

**Objective:** To determine the association of Arnica montana and blood loss, surgical field bleeding and operative time in endoscopic sinus surgery among adults with chronic rhinosinusitis with nasal polyposis.

### Methods:

**Design:** Single-Blinded Randomized Controlled Trial

**Setting:** Tertiary Government Hospital

**Participants:** Forty-one (41) adults aged 19-76 years old with chronic rhinosinusitis with nasal polyposis and meeting inclusion criteria were randomly divided into two groups, Arnica and control. The former took 5 sublingual Boiron® Arnica montana 30C pellets, 12 hours then 1 hour prior to surgery; the latter did not. Both groups had routine oxymetazoline and lidocaine-epinephrine decongestion. Intraoperative blood loss, surgical field bleeding quality and operative time were assessed by blinded surgeons and anesthesiologists.

**Results:** Mean estimated blood loss was 187ml (SD 100.14) for controls versus 72ml (SD 12.59) for the Arnica group; (p < 0.05). Mean operative time was 3.55 hours (SD 1.25) for controls and 3.44 hours (SD 1.57) for the Arnica group; (p=0.9). Surgical field bleeding was graded slight with 75% needing occasional suctioning (grade 2) and 25% needing frequent suctioning (grade 3) in the Arnica group, versus moderate bleeding with more frequent suctioning (grade 4) in 71% and slight bleeding but needing frequent suctioning (grade 3) in 29% of controls.

**Conclusion:** In this randomized clinical trial, Arnica montana was associated with less blood loss and less surgical field bleeding compared to controls, but there was no difference in mean operative times. Arnica montana may be effective in reducing blood loss and improving surgical field quality during endoscopic sinus surgery for chronic rhinosinusitis with nasal polyposis.

**Keywords:** *Arnica montana, hemostasis, surgical*

**Endoscopic sinus surgery (ESS)** is one of the most common operative ENT procedures, including for chronic rhinosinusitis with nasal polyposis. Visualization of the nasal anatomy is vital to the procedure, allowing complete dissection, and lessening complications. Bleeding from the nasal mucosa during ESS interferes with the surgical field, prolongs operative time, and increases the incidence of incomplete surgery. Hence, most surgeons agree that hemostasis is important.<sup>1</sup>

Several clinical trials have demonstrated different ways of controlling bleeding operatively during ESS using oxymetazoline, preoperative oral steroids, and tranexamic acid.<sup>2,3,4</sup> Arnica montana is a homeopathic medicine used by plastic and cosmetic surgeons to lessen postoperative edema and ecchymosis in rhinoplasty,<sup>5</sup> but studies are limited and none deal with ESS. We hypothesized that administering Arnica montana preoperatively to adult patients with chronic rhinosinusitis with nasal polyps may decrease blood loss, improve surgical field bleeding

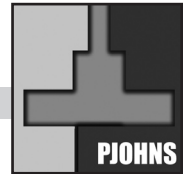
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quality and lessen operative time during endoscopic sinus surgery.

The aim of this trial is to determine the association of sublingual Arnica montana on estimated blood loss, surgical field bleeding and operative time in endoscopic sinus surgery among adults with chronic rhinosinusitis with nasal polyposis.

## METHODS

This single blind randomized controlled clinical trial was approved by our institutional ethics committee and conducted in a tertiary government hospital from January 2013 to July 2014. With written informed consent, all participants were recruited from the ENT-HNS outpatient department of our institution. The sample size of 40 was computed based on the institution out-patient department yearly census of endoscopic sinus surgery with a type 1 error of 0.05 and type 2 error of 95%. Inclusion criteria were adults aged 19 and above who satisfied the operational definition of grade 2 or 3 nasal polyposis with or without chronic rhinosinusitis undergoing functional endoscopic sinus surgery as defined by the PSO-HNS Clinical Practice Guidelines.<sup>4</sup> In addition, evidence of sinus mucosal disease and nasal polyps had to be demonstrated on sinus CT imaging and nasal endoscopy.

Patients with a history of hypersensitivity to Arnica montana, lactose intolerance, deranged bleeding parameters, cardiac and hematologic problems, and intake of aspirin, warfarin or other anti-coagulant medications were excluded from the study.

A total of 41 patients meeting inclusion criteria were recruited and informed consent was obtained. Subjects were randomly divided into 2 groups, the control and Arnica group, using simple randomization technique. Fish bowl method was used to classify "odd" and "even," with "odd" assigned to the control group and "even" to the Arnica group, resulting in a total of 21 controls and 20 in the Arnica group.

## Intervention

After a history was obtained and otorhinolaryngological physical examination performed, all participants had their bleeding parameters (prothrombin and partial thromboplastin time) checked pre-operatively. Patients more than 34 years old underwent medical risk assessment.

The Arnica group received 5 Boiron® Arnica montana 30C pellets (Boiron, Newtown Square, PA, USA) administered sublingually, 12 hours then 1 hour prior to procedure by the physician – investigator while the control group did not receive any. All surgeons and anaesthesiologists were blinded to the study.

All procedures were performed under inhalational general endotracheal anaesthesia using Sevoflurane and intravenous lactated Ringer's solution. Intraoperative mean arterial pressure was maintained at 60mmHg. Topical oxymetazoline 0.05% solution (PT Schering-Plough, Indonesia) and 2% lidocaine HCl + 1:100,000 epinephrine injection (Hospira, IL, USA) were used prior to surgery. Four different surgeons performed ESS by rotation using the Messerklinger technique. Different anaesthesiologists used the same anesthesia protocol for each patient. Cutting and grasping Blakesley (Karl Storz GmbH & Co., Germany) and

Takahashi (Karl Storz GmbH & Co., Germany) nasal forceps were used for all procedures. No microdebrider was used.

## Outcome Measures

The amount of estimated blood loss in milliliters was estimated by the anesthesiologist at the end of each procedure, by subtracting the total volume collected from the 500ml graded suction canister plus the volume per number of nasal strips used intraoperatively from the total volume of saline irrigation used intraoperatively. After the procedure the surgeon answered the Boezart<sup>6</sup> grading scale for scoring surgical field bleeding to grade the quality of the surgical field. Operative time was recorded in minutes.

## Data Analysis

Data was encoded on Microsoft Excel 2013 version 15.0 (Office 2013, Microsoft Corporation, Redmond, WA, USA) spreadsheets and analyzed. Data was presented in means and percentages. Statistical Analysis used a two-tailed Student T test and Chi square test were used to compare the control and Arnica group with a confidence interval of 95% and level of significance set at  $p < 0.05$ .

## RESULTS

A total of 41 participants, 19 males and 22 females aged 16 – 73 years old (mean, 42 years) participated in the study. Demographic analysis of age, gender, and polyp grade showed no significant differences between Arnica and control groups ( $p > 0.05$ ). All patients underwent surgery uneventfully without complications such as bleeding and hypertension.

The mean estimated blood loss for the control group was 187ml (SD 100.14) versus 72ml (SD 12.59) for the Arnica group; the difference was statistically significant ( $p < 0.05$ ). The mean operative time for the control group was 3.55 hours (SD 1.25) versus 3.44 (SD 1.57) for the Arnica group, although the difference was not statistically significant ( $p = 0.91$ ). In terms of the grading scale for scoring of surgical field bleeding, surgeons reported slight bleeding in the Arnica group wherein 75% needed occasional suctioning (grade 2) and 25% needed frequent suctioning (grade 3). On the other hand, surgeons reported that 71% of controls had moderate bleeding with more frequent suctioning (grade 4) and 29% had slight bleeding but needed frequent suctioning (grade 3). Outcome measures are summarized in *Table 1*.

## DISCUSSION

This study showed a significant decrease in the mean estimated blood loss and good surgical field bleeding quality during functional endoscopic sinus surgery in the Arnica montana group versus controls. The anti-inflammatory property of Arnica montana, *sesquiterpene lactones*, may have played a role in minimizing blood loss. Kawakami<sup>7</sup> et al. demonstrated *in vivo* decrease in histamine release causing decrease capillary permeability and an increase in diameter of lymphatic vessels causing less swelling using Arnica montana. Moreover, they

**Table 1.** Outcome measurements in two groups

	Control Group n=21	Arnica Group n=20	P-value
Age	40	44	0.412
Gender (male)	9	10	0.646
Nasal Polyp Grade			0.631
Grade 2	11	8	
Grade 3	10	12	
Estimated blood loss (ml)	187	72	5.31
Operative time (hrs)	3.5	3.5	0.25
Bleeding Score (N: %)			
0	0	0	
1	0	0	
2	0	15 (75%)	
3	6 (29%)	5 (25%)	
4	15 (71%)	0	
5	0	0	

concluded that the anti-inflammatory property of Arnica montana and dexamethasone was generally comparable.

Arnica montana is part of the *Compositae* plant family.<sup>1</sup> Its active ingredients *sesquiterpene lactones*, such as helenalin and dihydrohelenalin extracted from its disk flower and stem are responsible for its anti-inflammatory properties. It has anti-coagulation, anti-inflammatory, and analgesic effects.<sup>8</sup> This is supported by the *in vivo* findings of Kawakami<sup>7</sup> *et al.* that pre-treatment with Arnica montana in rats showed significant anti-edematous effect with less intense mass cell degranulation and greater diameter average of lymphatic vessels, however there was no significant difference in the cell infiltrate of polymorphonuclear and mononuclear cells seen in acute inflammation. Thus, there was no selective modulation of leukocytes but only vascular regulations.

Despite limited clinical trials on the efficacy of Arnica montana and its anti-inflammatory property, plastic and cosmetic surgeons use the drug. Intravenous Dexamethasone and oral Arnica montana were compared in the clinical trial of Totonchi and Guyuron<sup>5</sup> in grading postoperative edema and ecchymosis after rhinoplasty. Arnica montana demonstrated good results in reducing edema but did not show any decrease in the intensity of ecchymosis as seen in Dexamethasone. Moreover, significant results of both drugs were seen in the first 2-3 days postoperatively and eventually became insignificant.

Arnica montana is considered a generally safe homeopathic medication. Kawakami<sup>7</sup> established its peak onset of action to start at 30-180 mins after ingestion. Boiron Arnica montana 30C is available in pellets and is an over-the-counter drug for swelling, bruises, and muscle pains. Cosmetic and plastic surgeons use Arnica montana pellets to

lessen postoperative edema and ecchymosis.<sup>5</sup> The limited studies did not establish pharmacodynamic and pharmacokinetic properties nor did they address preclinical safety. Moreover, its safety for pregnant and breast feeding patients, adverse reactions and drug interactions have not been established.

Because research on the efficacy, drug action, and safety profile of Arnica montana is still limited, further studies are recommended. Additional limitations of this study include surgeon and anesthesiologist variations. Post-operative outcomes such as presence of residual or incomplete dissection and post-operative pain may also vary. Our study had no comparator or placebo and comparing Arnica montana with Tranexamic acid and/or corticosteroids may be considered for future studies. In addition, this study did not include bleeding parameters as part of the outcome measures because the study of Baillargeon<sup>1</sup> already showed no statistically significant effect on PT, PTT, platelet count, and procoagulant factor VIII after Arnica montana treatment.

In this randomized clinical trial, Arnica montana was associated with less blood loss and less surgical field bleeding during endoscopic sinus surgery compared to controls, but there was no difference in mean operative times. Arnica montana may be preoperatively effective in reducing estimated blood loss and improving surgical field quality during endoscopic sinus surgery for chronic rhinosinusitis with nasal polyposis.

**ACKNOWLEDGEMENTS**

We would like to thank the anesthesiologists and co-resident ENT surgeons, Dr. Michelle Angelica Cruz-Daylo, Waynn Destriza, Elaine Lagura, and Khristine Girado for participating in our study.

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