PICO Search Assignment Worksheet

30F, with no significant PMH, presents to the office to discuss an upcoming surgery. Patient states she has been diagnosed with a deviated septum that has been restricting her air intake and is scheduled for a rhinoplasty. Based on her own research over the internet, she has seen numerous patients develop significant edema and ecchymosis post operation. Her friend recommended arnica gel [arnica montana] following surgery to help reduce the swelling/bruising/pain but she is questioning whether it works at all.

<u>Search Question</u>: In patients undergoing rhinoplasty, how effective is the use of arnica montana to help reduce edema, ecchymosis, and/or pain following the procedure?

Question Type: What kind of question is this? (boxes now checkable in Word)

□Prevalence	□Screening	□Diagnosis
⊠Prognosis	⊠Treatment	□Harms

Assuming that the highest level of evidence to answer your question will be meta-analysis or systematic review, what other types of study might you include if these are not available (or if there is a much more current study of another type)?

Please explain your choices.

Along with meta-analyses or systematic reviews, prospective cohort studies along with randomized control trials are types of studies that I am interested in including. Studies that follow patients over a period of time provide higher quality evidence than studies that look back retrospectively on data to draw conclusions. RCTs test treatment strategies which is exactly what my question is all about.

PICO search terms:

Р	Ι	С	0
Adults	Arnica montana	None	Decreased
			swelling/edema
Rhinoplasty	Arnica gel	Placebo	Increased healing
	Oral arnica		Decreased pain
			Decreased
			bruising/ecchymosis

Search tools and strategy used:

Database	Terms	Filter	# of Articles
PubMed	Arnica montana rhinoplasty	Medline, last	11
		10 years	
ScienceDirect	Arnica montana rhinoplasty	Last 10 years	13
MEDLINE	Arnica montana rhinoplasty	last 10 years	1
Complete			

There was a plethora of articles and research related to arnica montana and its uses, however, not many were specific towards rhinoplasty and some articles mentioned arnica montana usage but for a general use post-operation and not specifically towards rhinoplasties. I tired to focus on articles that pertained to rhinoplasties specifically.

Results found:

Article 1

Citation:

Chaiet, S. R., & Marcus, B. C. (2016). Perioperative Arnica montana for Reduction of Ecchymosis in Rhinoplasty Surgery. Annals of Plastic Surgery, 76(5), 477–482. doi:10.1097/sap.00000000000312

https://sci-hub.se/https://doi.org/10.1097/sap.00000000000312

Article Type:

Randomized Control Trial

Abstract:

Background: Studies of homeopathic therapies to decrease postrhinoplasty ecchymosis have previously used subjective measurements, limiting their clinical significance. Recently, Arnica montana was shown to decrease postoperative ecchymosis after rhytidectomy, using an objective measuring tool. We believe that oral A. montana, given perioperatively, can be objectively shown to reduce extent and intensity of postoperative ecchymosis in rhinoplasty surgery.

Methods: Subjects scheduled for rhinoplasty surgery with nasal bone osteotomies by a single surgeon were prospectively randomized to receive either oral perioperative A. montana (Alpine Pharmaceuticals, San Rafael, Calif) or placebo in a double-blinded fashion. Ecchymosis was measured in digital "three-quarter" Yview photographs at 3 postoperative time points. Each bruise was outlined with Adobe Photoshop (Adobe Systems Incorporated, San Jose, Calif), and the extent was scaled to a standardized reference card. Cyan, magenta, yellow, black, and luminosity were analyzed in the bruised and control areas to calculate change in intensity. P value of G0.1 was set as a meaningful difference with statistical significance.

Results: Compared with 13 subjects receiving placebo, 9 taking A. montana had 16.2%, 32.9%, and 20.4% less extent on postoperative days 2/3, 7, and 9/10, a statistically significant difference on day 7 (P = 0.097). Color change initially showed 13.1% increase in intensity with A. montana but 10.9% and 36.3% decreases on days 7 and 9/10, a statistically significant difference on day 9/10 (P = 0.074). One subject experienced mild itching and rash with the study drug that resolved during the study period.

Conclusions: Arnica montana seems to accelerate postoperative healing, with quicker resolution of the extent and the intensity of ecchymosis after osteotomies in rhinoplasty surgery, which may dramatically affect patient satisfaction.

Key points:

- 22 subjects in RCT
- Compared using arnica vs a placebo
- Those who took arnica had statistically different appearances following post operative days
- Arnica seems to accelerate post-op healing which in turn improves patient satisfaction

Why I chose this article:

- I liked that the article was a RCT
- It specifically focused on my PICO question.
- Published in 2016
- Drawback to the article was that the sample size was quite small at only 22 participants in total with only 9 taking the arnica montana.

Article 2

Citation:

Lee, H. S., Yoon, H. Y., Kim, I. H., & Hwang, S. H. (2017). *The effectiveness of postoperative intervention in patients after rhinoplasty: a meta-analysis. European Archives of Oto-Rhino-Laryngology*, 274(7), 2685–2694. doi:10.1007/s00405-017-4535-6

https://sci-hub.se/https://doi.org/10.1007/s00405-017-4535-6

Article Type:

Meta-analysis

Abstract:

Rhinoplasty is the most common facial plastic surgical procedure, and the occurrence of periorbital edema and ecchymosis is normal after rhinoplasty. The goal of this study was to perform a systematic review with metaanalysis of the efficacy of postoperative care of edema and ecchymosis following rhinoplasty. Two authors independently searched the databases (PubMed, SCOPUS, Embase, Web of Science, and the Cochrane database) from inception to September 2016. We included studies that compared postoperative care methods (intervention groups) with no treatment (control group) where the outcomes of interest were edema, ecchymosis, and satisfaction rate of patients on postoperative days. Sufficient data for meta-analysis were retrieved for 11 trials with a total of 627 patients. Eyelid edema and ecchymosis during the first 7 days postoperatively were statistically decreased in the arnica administration groups versus the control group. Eyelid edema and ecchymosis during the first 24 h postoperatively were statistically decreased in the cold compression group versus the control group. The ratio of patient satisfaction was statistically higher in the tapping application group than in the control group. However, the analysis indicated that surgeons had a significant tendency to decrease intranasal packing. The administration of arnica, cold compression, and tape could reduce eyelid edema and ecchymosis. Intranasal packing was associated with more adverse effects in terms of postoperative ecchymosis compared to nonpacking. However, additional trials with thorough research methodologies should be conducted to confirm the results of this study.

Key points:

- 11 trials included in the meta analysis
- 627 patients included in the meta analysis
- Eyelid edema and ecchymosis during the first 7 seven days post-op that were treated with arnica saw statistically significant decrease versus the control group

Why I chose this article:

- It was a meta analysis
- Focused directly on my PICO question
- Published in 2017
- Had a good sample size of 600+ patients included in the analysis

Article 3

Citation:

Iannitti, T., Morales-Medina, J. C., Bellavite, P., Rottigni, V., & Palmieri, B. (2016). *Effectiveness and Safety of Arnica montana in Post-Surgical Setting, Pain and Inflammation. American Journal of Therapeutics, 23(1), e184–e197.* doi:10.1097/mjt.00000000000036

https://sci-hub.se/10.1097/MJT.000000000000036

Article Type:

Meta-analysis

Abstract:

Arnica montana has been widely used as a homeopathic remedy for the treatment of several inflammatory conditions in pain management and postoperative settings. This

review gives an overview of the therapeutic use of Arnica montana in the abovementioned fields also focusing on its mechanisms of action learned from animal models and in vitro studies. Arnica montana is more effective than placebo when used for the treatment of several conditions including post-traumatic and postoperative pain, edema, and ecchymosis. However, its dosages and preparations used have produced substantial differences in the clinical outcome. Cumulative evidence suggests that Arnica montana may represent a valid alternative to non-steroidal anti-inflammatory drugs, at least when treating some specific conditions.

Key points:

- Analysis included controlled clinical trials (with and without randomization), observational studies, and case series, but it excludes single case reports.
- In a randomized double-blind clinical study involving 48 primary rhinoplasty patients, oral Arnica (SinEcch) administered 3 times a day for 4 days vs 10 mg intravenous dexamethasone administered intraoperatively and followed by a 6-day oral tapering dose of methyl-prednisone significantly reduced edema rating, but not intensity and extent of ecchymosis at day 2 post-rhinoplasty when compared with the control group.
- At postoperative day 8, Arnica and control group showed significantly less extent and intensity of ecchymosis when compared with dexamethasone group. Furthermore, no differences in edema rating were observed among groups at this time point
- Arnica is more effective steroid/control group in treating post-operative settings
- Highly tolerable and could potentially replace NSAID usage especially in those with multiple medications thus decreasing risk of interaction between medications

Why I chose this article:

- This was a meta analysis
- Published in 2016
- It included many studies and covered a wide variety of surgical interventions but also included rhinoplasty which was what my PICO question is all about
- RCT pertaining to the rhinoplasty was double-blinded involving 48 patients

Article 4

Citation:

Knackstedt R, Gatherwright J. Perioperative Homeopathic Arnica and Bromelain: Current Results and Future Directions. Ann Plast Surg. 2020 Mar;84(3):e10-e15. doi: 10.1097/SAP.00000000002043. PMID: 31800557.

https://sci-hub.se/https://doi.org/10.1097/sap.00000000002043

Article type:

Systematic review

Abstract:

Introduction: Arnica and bromelain, two of the most widely recommended homeopathic medications to improve perioperative outcomes, have yet to be widely adopted by allopathic practitioners. A significant barrier to utilization of herbal medications by allopathic doctors is that the preparations and dosing regimens are not widely known or understood. The goal of this review was to critically analyze studies that have examined the perioperative efficacy of arnica and bromelain with a focus on treatment regimen and outcomes.

Methods: A triple database search was conducted with the keywords "arnica," "bromelain," and "surgery." References for each identified article were analyzed for additional articles. Articles were analyzed for methodology, outcomes, and conclusion. Articles were excluded if they did not involve human subjects, were published before 1990, and if they were not available in English. Level of evidence was determined based on methodology.

Results: A total of 29 articles met inclusion criteria, with 20 and 9 in the arnica and bromelain treatment groups, respectively. There was marked heterogeneity with regard to surgical procedure, dosing regimen, outcomes measured, and results. Arnica seems to have a mitigating effect on ecchymosis, most notably following rhinoplasty and facelifts/facial procedures. Bromelain is well supported across numerous studies in reducing trismus, pain, and swelling following molar extractions. However, there was no effect demonstrated when evaluating topical arnica following blepharoplasty procedures.

Discussion: A systematic review of the literature demonstrates the potential for arnica and bromelain to improve perioperative outcomes including edema, ecchymosis, and pain control. Future studies are required to determine safety and efficacy of dosing and interactions with other medications. We hope this article stimulates surgeons to consider using these interventions to improve perioperative outcomes in the context of well-done studies with an objective analysis of results.

Key points:

- 29 articles included in this review
- 20 articles pertained to arnica usage while 9 articles pertained to the usage of bromelain
- Arnica seems to have a mitigating effect on ecchymosis most notably following rhinoplasty/facial procedures
- Further studies are needed to determine safety and efficacy of dosing and interactions

Why I chose this article:

- It was a systematic review
- It included 29 articles
- Published in 2020
- Although it did not focus directly on my PICO question, it did include some valuable information that pertains to my question
- There was key result seen with use of arnica in rhinoplasties/facial procedures

What is the clinical "bottom line" derived from these articles in answer to your question?

Based on the evidence selected, the clinical bottom line here is that there are potential benefits to using arnica montana following rhinoplasties. Chaiet et al., concluded that arnica montana seemed to be accelerate post-op healing and thus improve patient satisfaction. Lee et al., witnessed a statistically significant decrease in edema and ecchymosis in the arnica montana group versus the control. Iannitti et al., concluded that the arnica group showed significantly less ecchymosis versus the dexamethasone group or placebo. Arnica demonstrated high tolerability which could potentially replace NSAID usage down the road one day. Knackstedt et al., concluded that arnica had a mitigating effect in relation to ecchymosis following rhinoplasties. There is some evidence out there to support the idea of using arnica montana especially following a rhinoplasty procedure. Due to its high tolerability in most patients, I think the patient in the above scenario should be able to use arnica montana following her procedure since she is worried about ecchymosis and edema. Due to the small sample sizes included in this articles, I think a larger scale study could give a clear definition as to how effective arnica montana can be not just for rhinoplasties but for all patients after any procedure for control of ecchymosis and edema.