

Evaluation of Whole Pomegranate Extract as Decongestant for Preparation before Diagnostic Rigid Nasal Endoscopy: a Double Blind Randomized Clinical Trial

Navid Ahmady Roozbahany¹, Farzad NikooSeresht¹, Mohammadali MohammadKhani¹, Mahbobeh Oroei¹

¹Hearing Disorders Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Article Info

Article note:

Received: Feb, 2016
Accepted: May, 2016

Corresponding Author :

Mahbobeh Oroei
Email:
dr.oroiei@gmail.com

Keyword:

Pain; Pomegranate; Nasal endoscopy

Abstract

Background: The use of rigid nasal endoscopy is one of the common methods to investigate anomalies and pathologies of nasal cavities in the patients with sinonasal symptoms.

Purpose: To identify the effect of whole pomegranate extract on pain relief during nasal endoscopy.

Methods: Adults candidate for rigid nasal endoscopy were enrolled from January 2015 to April 2015 in Loghman hospital. The patients were randomized in a double-blinded fashion, to receive two solutions; whole pomegranate extract(WPE) and shrinkage solution (SS) that was consisted of 5cc lidocaine 2% and 5cc phenylephrin 0.5 %. The principle outcomes were severity of pain and mucosal appearance during nasal endoscopy.

Results: A total of 41 patients (mean age: 40.05±12.92) were studied. There were no significant differences in severity of pain and mucosal appearance between both groups.

Conclusion: A new point in modern medicine is using traditional medicine as a complementary arm. The natural elements can be sometimes a good alternative. The pomegranate extract probably has constrictive effects and can be an alternative for vasoconstrictor drugs. There is a need for stronger research in this field.

Cite this article as: Ahmady Roozbahany N, NikooSeresht F, MohammadKhani M, Oroei M. Evaluation of Whole Pomegranate Extract as Decongestant for Preparation before Diagnostic Rigid Nasal Endoscopy: a Double Blind Randomized Clinical Trial. 2016; 2(2): 47-50.

INTRODUCTION

Since the invention of the rigid nasal endoscopy by Hopkins and Storz in 1959, this procedure has become one of the most common diagnostic tools in the domain of ENT specialty and nowadays this is a part of the routine examination in many patients with sinonasal symptoms rather in offices or in hospitals (1).

Using an endoscope, anomalies and pathologies of nasal cavities from nostrils till nasopharynx can be observed and the physician can also take samples if necessary. Most of the patients complain of pain, discomfort and sense of foreign body in the nose during nasal endoscopy. On the other hand, mucosal congestion and hyperemia can cause bleeding during the procedure and it can

also decrease the visual capabilities of the physician during the procedure(1, 2)

Plants have been utilized as medicine for thousands of years. There are many books from ancient civilizations of Iran, India and China about the effect of herbal medicine in treating many diseases. World Health Organization (WHO) named 252 kinds of essential drugs that 11% of them are made directly from plants or they have the herbal origin. Nowadays, there is a tendency to use herbal medications instead of synthetic drugs because synthetic medications are not accessible around the globe and in popular belief, herbal medications do not have the side effect of synthetic medications and the over use of them is believed to be virtually harmless (3-6).

Pomegranate is a botanical name for *Punicagranatum*. It is a fruit-bearing deciduous shrub or small tree. In Iranian herbal and traditional medicine, pomegranate has a constrictor effect. This effect is less in pomegranate juice and is higher in pomegranate skin (7).

In this study, we used whole pomegranate extract, which contains seeds, juice and skin of pomegranate as decongestant material before rigid nasal endoscopy.

PATIENTS and METHODS

In this double blind randomized clinical trial, 41 patients were evaluated in Loghman Hakim hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran. All of the patients referred to otolaryngology clinic who were candidate for rigid nasal endoscopy from January 2015 to April 2015 regardless of symptoms, entered the study. Two solutions were prepared and labeled with codes A and B. Material A was 10 cc of whole pomegranate extractand (WPE) and material B was consisted of 5cc lidocaine 2% and 5cc phenylephrin 0.5 % which is called shrinkage solution (SS). For making WPE we used 3 kilograms of pomegranate, we sliced them and then boiled them with 1000cc of water for 2 hours in a closed container, then we used this material as whole pomegranate extract. In each solution, we put 10 shrinkage bondage that was 10×1cm vibril cotton bondage. All the materials and bandages were made every day and they kept in a closed container in environment temperature. Randomly in one nasal cavity we put shrinkage material A and we put material B on the other side.

An ear nose throat resident performed all of the procedures of preparing the shrinkage material and putting the cotton pad in the nasal cavities of patients under the middle turbinate. All of interventions were assured by the investigator's direct observation.

The patient and endoscopist were blind about the side of the application of each material.

After five minutes the shrinkage bondages were brought out of nasal cavities and patient was referred to endoscopy room. After finishing the endoscopy, the patient and the physician filled a questionnaire about the pain and discomfort through endoscopy and the mucosal appearance of nasal cavity. The patient pain was evaluated in a scaled 0-10 by visual analog scale, which score 10 represents "severe" and score 0 the opposite. The severity of these variables were categorized to four level (score 0: no pain , score1-3: mild , 4-6 : moderate and 7-10 : sever).

All the data was gathered and analyzed with SPSS for windows version 20 (SPSS Inc., Chicago, IL). The continuous variable was described to mean and standard deviation. The qualitative variables were reported frequency and percentage. The variables were reclassified dichotomous and analyzed using McNemar's test. Statistical significant was defined less than 0.05. A written informed consent was obtained from the patients prior to the enrollment. The medical ethics committee of Shahid Beheshti University of Medical sciences, Tehran, Iran, approved the study.

RESULTS

In that period of time 41 patients entered the study that 23 of them were male (56%) and 18 were female (44%). The age of patients ranged between 16 and 75 years and mean age of patients was 40.05 ± 12.92 years. Twenty-one (51.2%) and 20 patients (48.8%) reported no pain during nasal endoscopy in shrinkage solution and whole pomegranate extract groups respectively. There was no significant difference in severity of pain between the two groups (table 1).

Only one patient had mucous hyperemia in WPE group. The appearance of nasal mucosa following application of WPE and SS were similar (p-value: 1.00).

Table 1: clinical outcomes in the two intervention groups

Variables		Shrinkage Solution (n= 41)	Whole Pomegranate Extract (n=41)	P-value
Severity of pain; n (%)	No pain	21(51.2)	20(48.8)	0.25
	Mild	17(41.5)	15(36.6)	
	Moderate	3(7.3)	2(4.9)	
	Sever	0(0.0)	4(9.8)	
Mucosal Appearance; n (%)	Normal	4(9.8)	3(7.3)	1.00
	Pale	37(90.2)	37(90.2)	
	Hyperemic	0(0.0)	1(2.4)	

DISCUSSION

According to Iranian traditional medicine opinion, pomegranate has the constrictor effect and this effect is more in its skin rather than seeds and juice (8-11).

Nasal endoscopy has a very important role in approach to nasosinusual symptoms, but most of the patients have pain and discomfort due to contact of the endoscope lens with the nasal mocusa. Cophenylcaine (phenylephrin +lidocain) is usually used as decongestant and anesthetic before the procedure but the bitter taste of lidocaine is not tolerable in some people, thus, making the endoscopy more annoying (1, 2, 12, 13).

Walsche et al. examined 33 patients and used cophenylcaine spray (containing lignocaine 5% (50mg/ml) and phenylephrine 0.5% (5mg/ml)) in one nasal cavity and cocaine 10%+adrenalin in the other side before rigid nasal endoscopy. They analyzed the pain and discomfort that the patients tolerated and there was no significant difference between two groups (14).

Douglas et al. examined 30 patients in two visits. They used cophenylcaine spray for one group before rigid nasal endoscopy in the first visit and lidocaine 2% spray in the second visit. In the other group, they did the opposite, lidocaine 2% in the first nasal endoscopy and cophenylcaine spray in the second visit. Subsequently, they gathered the data of pain that patients tolerated by visual analogue scale (VAS) of these two groups and there were no significant differences between these two groups (1, 15).

Pothier et al. in his study suggested that patients who applied the cophenylcaine spray 10 minutes before nasal endoscopy suffer less pain than patients using this spray one minute before nasal endoscopy (1, 16).

Most authors suggest that using decongestant material alone for preparing the patient before nasal endoscopy has the equal effect of decongestant and decreasing the pain by using the decongestant and anesthetic material together. Moreover, it also has no bitter taste of lidocaine (1).

Pomegranate originated in the region of modern-day Iran, and has been cultivated since ancient times throughout the Mediterranean region and northern India. The most abundant phytochemicals in pomegranate juice are polyphenols, including the hydrolyzab. Tannins called ellagitannins forms when ellagic acid and/or gallic acid binds with a carbohydrate to form pomegranate ellagitannins, also known as punicalagins. Compared to the pulp, the inedible pomegranate peel contains as much as three times the total amount of polyphenols, including condensed tannins, catechins, gallocatechins and prodelphinidins. A 100-gram serving of pomegranate seeds provides 12% of the daily value (DV) for vitamin C, 16% DV for vitamin K and 10% DV for folate. Pomegranate seed oil contains punicic acid (65.3%), palmitic acid (4.8%), stearic acid (2.3%), oleic acid (6.3%), and linoleic acid (6.6%)(17).

By reviewing the Iranian herbal medicine we found that pomegranate has been used as a

constrictor for many years and have proven effects.

By analyzing the data we found that there were no significant difference between standard material and pomegranate extract in reducing the pain during endoscopy and the mucosal appearance in both methods were the same. Therefore, pomegranate extract could be used as decongestant material in nasal mucosa.

CONCLUSION

Pomegranate extract has proven to have constrictive effects and has been used for many years. In otolaryngology we may need decongestants in many diagnostic and therapeutic procedures. Therefore, this study is the first step of using the pomegranate as mucosal decongestant and maybe in the future it can be used as an alternative for vasoconstrictor or decongestant drugs.

ACKNOWLEDGEMENTS

We would like to appreciate the support of Clinical Research Development Center of Lohman Hakim hospital, Tehran, Iran.

FUNDING/SUPPORT

None to declare.

CONFLICT of INTEREST

The authors declare no conflict of interest.

REFERENCES

1. Nankivell P, Pothier D. Nasal and instrument preparation prior to rigid and flexible nasendoscopy: a systematic review. *The Journal of Laryngology & Otology*. 2008;122(10):1024-8.
2. Chadha NK, Lam GO, Ludemann JP, Kozak FK. Intranasal Topical Local Anesthetic and Decongestant for Flexible Nasendoscopy in Children A Randomized, Double-blind, Placebo-Controlled Trial. *JAMA*. 2013;139(12):1301-5.
3. Balunas MJ, Kinghorn AD. Drug discovery from medicinal plants. *Life sciences*. 2005;78(5):431-41.
4. Phillipson JD. Phytochemistry and medicinal plants. *Phytochemistry*. 2001;56(3):237-43.

5. Rates SMK. Plants as source of drugs. *Toxicon*. 2001;39(5):603-13.
6. Gurib-Fakim A. Medicinal plants: traditions of yesterday and drugs of tomorrow. *Molecular aspects of Medicine*. 2006;27(1):1-93.
7. Sina I. The canon of medicine. Sharafkandi A, trans),[in Persian] Tehran. 1997:190-3.
8. Frosh A, Jayaraj S, Porter G, Almeyda J. Is local anaesthesia actually beneficial in flexible fiberoptic nasendoscopy? *Clinical otolaryngology and allied sciences*. 1998;23(3):259-62.
9. Leder SB, Ross DA, Briskin KB, Sasaki CT. A prospective, double-blind, randomized study on the use of a topical anesthetic, vasoconstrictor, and placebo during transnasal flexible fiberoptic endoscopy. *Journal of Speech, Language, and Hearing Research*. 1997;40(6):1352-7.
10. Sadek S, De R, Scott A, White A, Wilson P, Carlin W. The efficacy of topical anaesthesia in flexible nasendoscopy: a double-blind randomised controlled trial. *Clinical Otolaryngology & Allied Sciences*. 2001;26(1):25-8.
11. Jonas N, Visser M, Oomen A, Albertyn R, van Dijk M, Prescott C. Is topical local anaesthesia necessary when performing paediatric flexible nasendoscopy? A double-blind randomized controlled trial. *International journal of pediatric otorhinolaryngology*. 2007;71(11):1687-92.
12. Burton MJ, Altman KW, Rosenfeld RM. Extracts from The Cochrane Library Topical Anaesthetic or Vasoconstrictor Preparations for Flexible Fibre-optic Nasal Pharyngoscopy and Laryngoscopy. *Otolaryngology--Head and Neck Surgery*. 2012;0194599812444060.
13. Georgalas C, Sandhu G, Frosh A, Xenellis J. Cophenylcaine spray vs. placebo in flexible nasendoscopy: a prospective double-blind randomised controlled trial. *International journal of clinical practice*. 2005;59(2):130-3.
14. Walshe P, Rowley H, Hone S, Timon C. Co-phenylcaine as an alternative to Brompton's solution in rigid nasendoscopy: a pilot study. *Journal of clinical pharmacy and therapeutics*. 2002;27(3):185-7.
15. Douglas R, Hawke L, Wormald PJ. Topical anaesthesia before nasendoscopy: a randomized controlled trial of co-phenylcaine compared with lignocaine. *Clinical Otolaryngology*. 2006;31(1):33-5.
16. Pothier D, Awad Z, Whitehouse M, Porter G. The use of lubrication in flexible fiberoptic nasendoscopy: a randomized controlled trial. *Clinical Otolaryngology*. 2005;30(4):353-6.
17. Healthcare T. PDR for herbal medicines. Montvale: Thomson Healthcare; 2004.