

### RESEARCH ARTICLE

## Effectiveness Test of The Use of Nigella Sativa Oil Compared with Sodium Docusate as A Therapy for Cerumen Impaction on Children at Puteri Aisyiyah Medan Orphanage in Vitro

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**Abstract:** Introduction: Cerumen Impaction is a hearing problem that most often results in decreased hearing function and ear pain. Treatment using natural ingredients is widely practised. One of them is the use of Nigella sativa Oil. The purpose of this study was to analyze the effectiveness of using Nigella sativa Oil and sodium docusate as a treatment for impaction of cerumen in children at the Puteri Aisyiyah Orphanage in Medan City in vitro at 5,10,15 and 30 minutes. This type of research was a eksperimental study in vitro which in practice uses a probability sampling technique, namely simple random sampling on existing groups. Significance value of 0.000(p < 0.05). So it can be stated that the use of the Nigella Sativa Oil solution and the Docusate Sodium solution have different effectiveness, while this difference can be seen from the Mean  $\pm$  Deviation Standard value in each group, where the Nigella Sativa Oil solution has a higher Mean  $\pm$  Deviation Standard value (0.788  $\pm$  0.144) compared to sodium docusate solution (0.145  $\pm$  0.125). The conclusion is that the use of Nigella Sativa Oil has significant effectiveness for the treatment of impaction of cerumen and the use of Sodium Docusate does not have significant effectiveness for the treatment of impaction of cerumen in children.

Keywords: Cerumen impaction; nigella sativa oil; sodium docusate

#### INTRODUCTION

The most common hearing problem that results in hearing loss and ear pain is called earwax impaction.<sup>1</sup> Earwax

accumulation caused by failure of the ear's self-cleaning mechanism is the most common reason for patients to seek medical care at a healthcare facility. Earwax



impaction is the most common reason for patients to visit a healthcare facility and occurs in 10% of children, 5% of healthy adults, 57% of elderly people in nursing homes, and one-third of people with mental retardation.<sup>2</sup> In 2012, the diagnosis of earwax impaction was seen in up to 5% of patients visiting healthcare facilities and approximately \$50 million was spent on earwax removal procedures in the United States. In addition, in populations at high risk of cerumen impaction such as the elderly and people with growth disorders, it is difficult to diagnose and receive treatment. 3,4

WHO data (2018) states that more than 5% of the world's population (466 million) experience hearing loss, of which 432 million are adults and 34 million are children. 5 Around 12 million people go to health facilities due to cerumen problems and 8 million of them undergo cerumen removal procedures in the United States.<sup>3</sup> An estimated 2-6% of the general population in the UK suffers from cerumen impaction at any given time. 6 An estimated 6-20% of high-risk populations such as the elderly and people with special needs experience cerumen impaction and are estimated to spend the same costs as the United States in cerumen removal procedures due lifestyles relatively similar between neighbouring countries in Australia. 4

RISKESDAS (2013) explains that of the Indonesian population aged five years and over, 2.6% have hearing loss, 0.09% are deaf, 18.8% have cerumen blockages, and 2.4% have secretions in the ear canal.<sup>7</sup> The prevalence of cerumen impaction in South Kalimantan is 25.5%. According to the Ministry of Health of the Republic of Indonesia (KEMENKES RI) in 2013, through a study conducted by the Faculty of Medicine, University of Indonesia (FK UI) in several schools in six cities in Indonesia, the prevalence of cerumen impaction in school children is quite high, namely 30-50%.7 In 2019, out of 262 first-grade elementary school students in five schools in the coastal area of North Semarang, 50.8% of them experienced cerumen impaction. It is known that at the age of 7 years, sebaceous gland production increases, with increasing age the level of cerumen production will decrease and then increase again in old age.8 Meanwhile, in Medan City, research related to the prevalence of cerumen impaction is still lacking.

Cerumen impaction is divided into two types, namely dry type and wet type. Drytype cerumen has hard and brittle characteristics is yellow to greyish and is often found in individuals of Asian descent. Meanwhile, wet-type cerumen has sticky and slippery characteristics is brownish and can turn dark when exposed to open air, often found in white and black individuals. Cerumen impaction occurs due to several factors, firstly due to changes in the anatomy of the ear canal that inhibit the release of cerumen. Secondly, excessive keratin production causes infection and deafness. Thirdly, in modern times humans are accustomed to eating quickly so the ear's



ability to clean cerumen itself with jaw movement when chewing becomes less effective. <sup>9,10</sup> There are several types of cerumenolytic agents, including water-based, oil-based, and non-water or oil-based. According to research conducted in 2020, research was conducted on various types of cerumenolytic agents on cerumen, it was found that sodium docusate has high effectiveness as a therapy for removing cerumen impaction. <sup>1,2,4</sup>

Currently, treatment using natural ingredients is widely practised. One of them is the use of Nigella sativa Oil. Nigella sativa Oil or black cumin oil is a spice that is often used as a cooking spice and has been known as a traditional medicine since ancient times. The content of Nigella sativa Oil, such as thymoquinone, functions as an antioxidant, anti-inflammatory, antimicrobial, immunomodulator. 11 According to research conducted in 2019, an in vitro study was conducted on patients with otitis media and externa using Nigella sativa Oil, it was found that Nigella sativa Oil is effective and can be an alternative treatment for ear infections because it provides antimicrobial effects against several microbes that cause ear infections. 12 In another study conducted in guinea pigs with tympanic membrane perforation were divided into three treatment groups. In the group of Dutch mice treated with Nigella sativa Oil topically and orally, improvements were found compared to the control group treated with saline topically.<sup>13</sup>

In the description, the prevalence of cerumen impaction in the world, especially in Indonesia, is still very high and occurs in various groups. Various studies have been conducted to find the right therapy in the cerumen impaction. management of Therefore, researchers are interested in researching the effectiveness of the use of Nigella sativa Oil and sodium docusate as cerumen impaction therapy in vitro in children at the Puteri Aisyiyah Orphanage in Medan City. The purpose of this study was to analyze the effectiveness of the use of Nigella sativa Oil and sodium docusate as cerumen impaction therapy in children at the Puteri Aisyiyah Orphanage in Medan City at minutes 5, 10, 15, and 30.

### **METHOD**

This type of research is an in vitro laboratory research which in its implementation uses a probability sampling technique, namely simple random sampling in existing groups. In the preparation stage, a search for valid literature was carried out that could help the research and obtain Ethical Clearance from the Research Ethics Committee of the Faculty of Medicine, University of Muhammadiyah, North Sumatra. Furthermore, a proposal was prepared to carry out the research. At the implementation stage, it will according to the work plan that has been prepared as well as possible in preparation stage. The stages of implementing the research start from observing the location taking cerumen and



treating cerumen in vitro in the laboratory. The last stage is analyzing the research data, compiling a research report and publishing it.

### **Population and Sample**

The population in this study were all children of the Aisyiyah orphanage, st. Santun No.17, Medan, North Sumatra, totaling 80 people. Determination of the number of samples in this study was carried out using the sample size formula for experimental research. The calculation of the sample size uses the minimum sample size which aims to test the hypothesis of the difference in the two proportions of the independent variable groups so that the n1 value is 24 research subjects. Place and Time of Research Samples were taken at the Aisyiyah orphanage, st. Santun No. 17, Medan, North Sumatra. In vitro laboratory test examinations were carried out at the Biochemistry laboratory, Muhammadiyah University of North Sumatra, Medan and started from November to December 2022.

### **Data Analysis**

The existing data will be tested for normality first. If the data is normally distributed, the data is tested with parametric tests, namely Independent Sample T-test and One Way ANOVA. If the data is not normally distributed, the data is tested with non-parametric tests, namely Kruskall Wallis and Mann Whitney to determine the comparison of the effectiveness of the two test solutions and the comparison of cerumen absorbance values in intervals of 5, 10, and 15, and 30 minutes.

### RESULT

### **Univariate Analysis**

Analysis univariate is a description change disintegration earwaxat the 5, 10, 15, and 30 minutes after being given the Nigella Sativa solution Oil and Sodium Docusate solution, Table 1 below explains the average absorbance of cerumen.

**Table 1. Average Cerumen Absorbance** 

		T		
Solvent	5	10	15	30
	minutes	minutes	minutes	minutes
Nigella				
Sativa Oil	0,751	0,775	0,799	0,828
Sodium				
Docusate	0,112	0,171	0,160	0,139

In table.1 above, the average absorbance of cerumen can be seen. Who were given a solution of Nigella Sativa Oil which showed an increase in time to time. While the average absorbance of the cerumen given the solution Sodium Docusate only increased from 5 minutes to 10 minutes, then experienced a decline starting from 10 minutes to the minute 15 and 30 minutes

### **Normality Test**

Normality tests are carried out to determine whether further testing uses statistics parametric or statistics non-parametric. Based on the normality test using *Shapiro Wilk*, all data groups at each time were not normally distributed, so test



comparison on every group used nonparametric statistics, in this matter is Kruskall Wallis and Man Whitney.

## Effectiveness use of *Nigella Sativa Oil* as therapy impaction earwax in children at the Puteri Aisyiyah Orphanage in Medan Cityin vitro at 5, 10, 15, and 30 minutes

In this section, we will conduct a test of the effectiveness of using Nigella Sativa. Oil use *Kruskal Wallis*. Following are the results testing *Kruskal Wallis*:

Table 2. Effectiveness of Nigella Sativa Oil

Mean ±					
<b>Time Standard Deviation</b>					
	(L/mol.cm)	N	<i>p</i> -value		
	5				
Nigella Sativa Oil	Minute $0.751 \pm 0.152$	24			
	10				
	Minute $0.775 \pm 0.146$	24	- 0.004		
	15		— 0,004		
	Minute $0.799 \pm 0.141$	24			
•	30				
	Minute 0.828±0.140	24			

Results testing *Kruskal Wallis* on Table 2, show The use of *Nigella Sativa Oil* is effective as a therapy for cerumen impaction in orphanage children. Puteri Aisyiyah of Medan City in vitro at the 5, 10, 15, and 30 minutes.

Based on the results of *Kruskall Wallis* which showed the use of Nigella Sativa Oil has effectiveness at 5, 10, 15, and 30 minutes, then Next, a further test (postdoc) was carried out to see at what minute Nigella Sativa solution showed its

effectiveness. The following are the results of further tests with *Man Whitney*.

**Table 3. Further Test Results** 

	Mann Whitney (P-Value)				
	5	10	15	30	
	Minute	Minute	Minute	Minute	
5	•				
Minute	-				
10					
Minute	0,170	-			
15					
Minute	0,019	0,190	-		
30					
Minute	0,002	0,016	0,197	-	

P in Table.3 shows that at 5 and 10 minutes there was no significant difference in usage of Nigella Sativa Oil, then absorbance earwax on minute 15 after given a solution of Nigella Sativa Oil experienced significant effectiveness, so also with the 30 minutes. Thus it can be stated that the cerumen given solution Nigella Sativa Oil's effectiveness is significant starting from 15 minutes.

Effectiveness use of Sodium Docusate as therapy impaction earwax in children at the Puteri Aisyiyah Orphanage in Medan Cityin vitro at 5, 10, 15, and 30 minutes

In part, This will test the effectiveness of Sodium Dokusat using *Kruskall Wallis*. Here are the results of testing *Kruskal Wallis*.



Table 1	Effectiveness	of Sodium	Docuesto
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Mean ± Time Standard Deviation N (L/mol.cm)			<i>p-</i> value	
	5 minute	$0.112 \pm 0.076$	24	
Sodium	10 minute	$0.171 \pm 0.173$	24	
Docusate	15 minute	$0.160 \pm 0.141$	24	0.482
	30 minute	$0.139 \pm 0.113$	24	

Results testing *Kruskal Wallis* on Table.4 shows a significance bigger than  $\alpha$  (0.05). So that the results test effectiveness can state not have a significant effect, meaning the use of Sodium Docusate can't work effectively as a therapy for cerumen impaction on orphanage children Puteri Aisyiyah Medan City's in vitro care at the 5, 10, and 15, and 30 minutes.

# Comparison between the Use of Nigella Sativa Oil and Sodium Docusate as Therapy for Cerumen Impaction in Children at the Aisyiyah Orphanage in Medan City

In this section, a comparison will be tested between the use of *Nigella Sativa Oil* with Sodium Docusate as a therapy for cerumen impaction using a test by *Man Whitney*. Following results testing *Man Whitney*.

Table 5. Comparison between *Nigella Sativa Oil* with Sodium Docusate

Mean ±		
Standard Deviation		
(L/mol.cm)	N	p-value
Nigella		_
Sativa Oil $0.788 \pm 0.144$	24	0.000

Sodium			
Docusate	$0.145\pm0.125$	24	

Table 5 shows the values significance as big as 0.000 (p < 0.05). So that can stated that the Use of Nigella Sativa Oil solution and the use of Sodium Docusate solution own effectiveness different in therapy impaction earwax, as for difference can seen from mark mean in every group, where the Nigella Sativa Oil solution has a higher mean value compared to Sodium Docusat solution. With this, It was concluded that Nigella sativa Oil has greater absorption effectiveness. Tall than sodium docusate against cerumen.

### **DISCUSSION**

### Effectiveness of Nigella Sativa Oil as In Vitro Therapy for Earwax Impaction

Earwax impaction is defined as the accumulation of earwax that causes symptoms or something that can complicate the examination of the ear canal, tympanic membrane. audiovestibular system both.<sup>3,6</sup> Earwax impaction is the accumulation of earwax that causes symptoms, such as hearing loss, feeling of fullness in the ear, otorrhea, tinnitus, dizziness, and other symptoms. Earwax impaction is the process of excessive earwax formation influenced by the narrow and winding shape of the ear canal, the viscosity of earwax, and repeated irritation due to the habit of cleaning the external ear canal.<sup>2,9</sup>

Nigella sativa Oil is used for many health problems is used as an alternative to



traditional medicine has been proven effective against various types of bacteria.<sup>12</sup> Nigella sativa is a medicinal plant from the Ranunculaceae family. Also known as black cumin or black seed, which is famous for its culinary uses, and historically valuable in traditional medicine. Black cumin is native to a large area of the eastern Mediterranean, North Africa, the Indian subcontinent, and Southwest Asia, and is cultivated in many countries, including Egypt, Iran, Greece, Syria, Albania, Turkey, Saudi Arabia, India, and Pakistan. Nigella sativa is a potent medicine and is often packaged in various forms, such as essential oil, paste, powder, in extract form, and has been indicated as a traditional treatment for a variety of diseases and conditions.11

The results of the study that have been conducted indicate that the use of Nigella Sativa Oil can work effectively as a therapy for cerumen impaction in children at the Puteri Aisyiyah Orphanage in Medan City in vitro at the 5, 10, 15, and 30-minute, this is proven by testing using Kruskall Wallis which obtained a significance figure (p-value) of 0.004 (p < 0.05). In addition, in this study, the use of Nigella Sativa Oil showed the best effectiveness at 15 and 30 minutes. At the 15-minute, the average absorbance was 0.799, while at the 30th minute, the average absorbance was 0.828.

This study is in line with previous research conducted by Kocoglu., et al (2019) on patients with otitis media and externa using Nigella sativa Oil, in which the study found that Nigella sativa Oil is effective and

can be an alternative treatment for ear infections because it provides antimicrobial effects against several microbes that cause ear infections.<sup>12</sup> Then a study conducted in 2016 on 14 Dutch mice showed that administering Nigella sativa Oil topically or orally had the effect of suppressing inflammation and inhibiting fibroblastic activity in the lamina propria of Dutch mice experiencing myringosclerosis.<sup>13</sup>

The use of Nigella sativa has various functions, such as antioxidant, antiinflammatory immunomodulator, anticancer, neuroprotective, antimicrobial, antihypertensive, cardioprotective, antidiabetic, gastroprotective, and nephroprotective hepatoprotective and properties. Nigella sativa has the main content of thymoquinone (TQ), thymocytehydroquinone, thymol, carvacrol, nigellone, nigericin, and α-herein, which are largely responsible for its pharmacological effects and therapeutic benefits. Nigella sativa has been evaluated in clinical trials with various health conditions such as hyperlipidemia, diabetes mellitus, hypertension, asthma, allergies, cough, bronchitis, fever, headache, infertility, rheumatoid arthritis and digestive diseases. 11

However, this study is not in line with the study conducted by Syahrijuita (2011) which explained that the basic ingredient of oil is fat. The study explained that the use of spectrophotometers in vitro using fat/oilbased materials turned out to be less effective in dissolving cerumen. In some communities, giving cerumenolytics can



reduce complaints of blocked ears due to cerumen. The use of oil is considered less effective because the function of oil tends to be a softener and does not cause disintegration of the cerumen bolus. <sup>14</sup>

### **Effectiveness of Docusate Sodium as In Vitro Cerumen Impaction Therapy**

Sodium Docusate is a water-based ear drop. This type of medicine is available in several brand options. Trade and easily available at pharmacies. This drug is used as a treatment for disturbance hearing light consequence density earwax ear or ingress of foreign objects. Method use sodium document is method tilt your head and drip enough drops into the ear canal for two minutes. Consecutive days – participate. <sup>15</sup>

The results of the study that have been conducted with univariate analysis show the average absorbance that the use of Sodium Docusate has effectiveness at the 5minute (0.112), 10-minute (0.171), 15minute (0.160), and 30-minute (0.139)against in vitro cerumen intervention, this is proven by testing using Kruskall Wallis which obtained a significance figure (pvalue) of p = 0.428. So it is concluded that the use of Sodium Docusate has no significant effect. Then based on a test comparison between the use of Nigella Sativa Oil with Sodium docusate use test Man Whitney showed results Which different significant, Where Nigella sativa Oil own effective absorbance Which more taller than sodium docusate against cerumen.

The results of this study are not in

line with the research of Piromchai et. al. (2020) which explained the results of the study of sodium docusate as a cerumenolytic agent that is widely used in medication and is prescribed by doctors in many countries including the UK and Thailand. There are controlled trials with random sampling, that found the effectiveness of sodium docusat in removing dirt ear until 90% and has an active role in cerumen impaction therapy. <sup>16</sup> According to research conducted in 2020, research conducted on various types of agent cerumenolytic to earwax, found that sodium docusat's effectiveness is as high as therapy appointment impaction cerumen. <sup>1,2,4</sup>

In Sodium Docusate there are several active substances. The function of the active substance can be used as an earwax softener. The process of softening the earwax in the ear will make it easier for earwax to come out because the substance in the ear will turn into a semi-solid. If Sodium Docusate is swallowed, it will certainly experience side effects and its effectiveness has been tested to cause inflammation of the digestive walls in the body. This is because Sodium Docusate is an external medicine and is not recommended for consumption. <sup>15</sup>

### Comparison of In Vitro Cerumen Absorption to *Nigella Sativa Oil Intervention* with Sodium Docusate

Results test comparison between use Nigella Sativa Oil with Sodium docusate use test Man Whitney show results Which different significant, Where Nigella sativa Oil own effectiveness absorbance Which



more tall than sodium docusate against cerumen, this is proven by testing using Mann Whitney which obtained a significance figure (p-value) of p = 0.000. Nigella Sativa Oil cerumenolytic has a higher effectiveness compared to sodium docusate on cerumen absorbance in vitro.

Based on the average absorbance of cerumen in this study, the comparison of results shows that *Nigella Sativa Oil* has better results compared to Sodium Docusate, seen at minutes 5, 10, 15, and 30 having a significantly different average result between the two interventions where the most effective contact is at minute 30 with the results of *Nigella Sativa Oil* having a value of 0.828) while Sodium Docusate has a value of 0.139.

The results obtained prove that the cerumenolytic longer the time of intervention of Nigella Sativa Oil with greater cerumen in vitro, the disintegration of cerumen fragments that will be absorbed, while Sodium Docusate has an absorbance value that is much different from Nigella Sativa Oil. This is reinforced by previous research obtained cerumen intervention in vitro at 30 minutes with water-based cerumenolytics, namely phenol glycerol 10% (0.2362) and sodium docusate (0.2198) compared to oilbased cerumenolytics, namely olive oil (0.0866) and coconut oil (0.0382) using a spectronic 21 spectrophotometer. 17

This study is in line with the study conducted by Kocuglu et al (2019) which explained that in the treatment process of patients with ear infections, drugs based on *Nigella Sativa Oil can be used*. This is because *Nigella Sativa Oil* has been clinically proven in the treatment process against bacterial strains. <sup>12</sup> Other studies have shown that *Nigella Sativa Oil* is a source of biologically active compounds that contribute to its antimicrobial properties and has been proven to be useful as a therapy for earwax impaction. <sup>13</sup> More recent studies have found that Earwax has a bactericidal effect on certain strains of bacteria that are composed of 60% keratin and saturated fatty acids. *Nigella Sativa Oil Earwax* can overcome these problems. <sup>18</sup>

The ability of *Nigella sativa oil* as an antibacterial is due to the active substance contained in it that is thymoguinone, thymol and tannin. Thymoquinone is thought to be able to form irreversible complexes with nucleophilic amino acids. Bacterial protein thus causing protein inactivation. Then thymol which is contained in oil caraway black own activity. The mechanism of phenolic compounds as antimicrobial substances is by poisoning protoplasm, damaging wall cells, and obtaining protein cell microbes. Meanwhile, tannins have galloyl groups and pyrogallol groups which react with protein membrane bacteria resulting in the damaged membrane cytoplasm Gram-negative bacteria such as S. typhi, so that the membrane functions as a barrier selective permeability, active transport, and regulating the internal composition of cells. Damaged, matter results in macromolecules And ions go out



from the cell, Then damaged cells experience death. 19, 20, 21

Another study related to Sodium Docusate was conducted by Dharmaratne (2020) which explained that Sodium Docusate is effective in the therapy of cerumen impaction. This is different from the research that has been conducted by researchers. The difference is thought to be because in previous studies several other compounds reacted with Sodium Docusate, such as 10% carboglycerin, where the main function of this carboglycerin is to soften earwax that collects in the ear of an individual. <sup>17</sup>

The ability of Sodium Docusate which has several active substances can be used as an earwax softener. The process of softening the earwax in the ear will make it easier for earwax to come out because the substance in the ear will turn into a semi-solid. If Sodium Docusate is swallowed, it will certainly experience side effects and its effectiveness has been proven to cause the digestive walls in the body to experience inflammation. <sup>15</sup>

### **Research Limitations**

In this study there are several limitations, namely:

- 1. The content of the two solutions used has different units. *Nigella Sativa Oil* contains 100% *Nigella sativa*, while in sodium docusate each millilitre of sodium docusate solution contains 5 milligrams of sodium docusate.
- 2. No identification of the level of cerumen hardness was carried out

when the intervention was carried out on the solution used.

### **CONCLUSION**

The research conducted concludes that the use of Nigella Sativa Oil has significant effectiveness on cerumen impaction therapy in children at the Puteri Aisyiyah Orphanage in Medan City at the 5th, 10th, 15th, and 30th minutes, and the use of Sodium Docusate does not have significant effectiveness on cerumen impaction therapy in children at the Puteri Aisyiyah Orphanage in Medan City at the 5, 10, 15, and 30 minutes.

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