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The effectiveness of rivanol tampon® compared with burowi tampon in acute diffuse otitis externa

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ABSTRACT

I Wayan Marthana Kedel, Edhie Samodra, Bambang Udji Djoko Rianto - ***The effectiveness of rivanol tampon® compared with burowi tampon in acute diffuse otitis externa (ADOE) patients***

Background: Acute diffuse otitis externa (ADOE) is one of the common diseases in ENT Department, Dr. Sardjito Hospital, with the frequency of 9-12%. The most common microorganism found is *Pseudomonas aeruginosa*. Infection usually occurrs after taking a bath, washing hair, and scratching the external ear canal. Treatment of acute diffuse otitis externa which consists of topical preparations, i.e. antibiotics and antiinflammation tampon or ear drop, is relatively expensive. A rationale, high recovery rate, cheap, and easily found preparation is needed. Burowi solution is one of the recommended treatment, but it is less popular.
Objective: The goal of this study was to know the effectiveness of Rivanol® tampon compared with Burowi tampon in acute diffuse otitis externa.
Methods: A randomized single-blind controlled trial (RCT) was performed at the outpatient clinic of ENT Department of Dr Sardjito General Hospital, Yogyakarta. Sixty-five subjects who were diagnosed as ADOE who met inclusion criteria were randomly allocated into two groups, that is, Rivanol® group and Burowi group. The ear canal was cleaned, and then Rivanol® tampon or Burowi tampon was applied. Evaluation was performed on day 3 and 5. Primary outcome was the recovery rate, and secondary outcomes were adverse reaction and marginal cost-effectiveness.
Results: Of 65 subjects, 33 were allocated into Rivanol® group and 32 were allocated into Burowi group. The recovery rate in Rivanol® group was 75.4%, while in Burowi groups was 49.3%. The difference in recovery rate between the two groups was statistically significant (p: 0.018; RR 4.350; 95% CI 1.225-15.442). Adverse reaction in Rivanol® group was dampness and soggy feeling in the ear canal (1.5%), while in the Burowi group the adverse events were pain and burnt sensation in the ear canal (3.1%), but they could be tolerated and disappeared on day 5. Analysis on marginal cost-effectiveness showed that the cost to cure one acute diffuse otitis externa patient with Rivanol® tampon was Rp 1,000.
Conclusion: Rivanol® tampon was more clinically effective and more cost-effective than Burowi tampon for acute diffuse otitis externa treatment.

Key words: acute diffuse otitis externa, Rivanol®, Burowi, clinical and cost effectiveness

ABSTRAK

I Wayan Marthana Kedel, Edhie Samodra, Bambang Udji Djoko Rianto - ***Keefektivan tampon rivanol® dibanding tampon burowi pada otitis eksterna difus akut.***

Latar Belakang: Otitis eksterna difus akut merupakan salah satu penyakit yang sering ditemukan di Bagian THT, Rumah Sakit Dr. Sardjito, Yogyakarta, dengan frekuensi sebesar 9-12%. Mikroorganisme yang tersering ditemukan adalah *Pseudomonas aeroginosa*. Infeksi biasanya terjadi setelah mandi, keramas, dan menggaruk liang telinga luar. Terapi otitis eksterna difus akut berupa preparat topikal yang terdiri dari antibiotika dan tampon antiinflamasi atau tetes telinga, adalah relatif mahal. Diperlukan preparat yang rasional, menimbulkan kesembuhan yang tinggi, murah, dan mudah didapat. Tampon larutan Burowi merupakan salah satu terapi yang dianjurkan tetapi kurang popular.
Tujuan: Tujuan penelitian adalah mengetahui keefektivan tampon Rivanol® dibanding tampon Burowi pada otitis eksterna difus akut.

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Metoda : Dilakukan trial kontrol buta acak di Poliklinik Bagian THT Rumah Sakit Dr. Sardjito, Yogyakarta. Lima puluh enam subjek dengan diagnosis otitis media eksterna akut yang memenuhi kritera inklusi dialokasikan secara random dengan komputer ke dalam 2 kelompok, yaitu : kelompok Rivanol® dan kelompok Burowi. Saluran luar telinga dibersihkan, dan kemudian di beri tampon Rivanol® atau Burowi. Evaluasi dilakukan pada hari ke-3 dan 5. Luaran primer adalah angka kesembuhan, dan sekunder reaksi tidak baik dan keefektivan-biaya marginal.
Hasil: Dari 65 subyek, 33 masuk dalam kelompok Rivanol® dan 32 dalam kelompok Burowi. Angka kesembuhan pada kelompok Rivanol® adakah 75,4%, sedangkan pada kelompokBurowi 49,3%. Ditemukan perbedaan bermakna antara dua kelo,pok (p = 0,018, RR 4,350, dan IK 95% 1,225 ; 15,442). Efek kurang baik pada kelompok Rivanol® adalah *"dampness and soggy feeling"* ? pada liang telinga (1,5%), sedangkan pada kelompok Burowi adalah rasa nyeri dan panas di liang telinga (3,1%), tetapi efek tadi dapat ditoleransi dan menghilang pada hari kelima. Analisis keefektivan-biaya marginal menunjukkan bahwa untuk menyembuhkan satu pasien dengan otitis eksterna difus akut dengan Rivanol® adalah Rp 1.000,—
Simpulan : tampon Rivanol® dari segi klinis maupun biaya lebih efektif daripada tampon Burowi untuk terapi otitis eksterna disfus akut.

INTRODUCTION

Acute diffuse otitis externa (ADOE) is ear inflammation affecting the skin of external ear canal, characterized by ear pain, hearing loss, and tinnitus. According to Mawson, acute diffuse otitis externa is the infection of the whole external ear canal with the symptoms of irritation, otorrhea, uncomfortable sensation, and swelling.[1,2] Other researcher defines acute diffuse otitis externa as the infection of superficial skin of external ear canal, outer layer of tympanic membrane, and auricula, with symptom of itching, sensation pain when masticating or opening the mouth, fever, and hearing loss, and objective signs of hyperemia, edema, and debris or pus in external ear canal. The signs and symptoms are difficult to differentiate with early stage of malignant otitis externa.[3,4]

Diffuse otitis externa consists of 3 stages: 1) pre-inflammatory phase, 2) acute inflammatory stage, and 3) chronic stage. Other author classifies diffuse otitis externa into acute, subacute, and chronic stages.[1,5,6]

Acute diffuse otitis externa is the most brevolent otitis externa commonly found in hot climate and high humidity areas. Acute diffuse otitis externa is also referred to as hot weather ear, Singapore ear, Hongkong ear, and swimmer's ear.[2,6,7,8]

At the end of 19th century and at the beginning of 20th century, there were many reports of otitis externa cases. Gill found 5-40% patients with otitis externa. Johnston reported that a third of ENT examinations in South America showed otitis externa, and he also reported that in the examinations of 70,000 soldiers in 1946 showed that 9.3% of 8,4321 outpatients and 8.1% of 2,382 inpatients had otitis externa. Conley reported 4.3% of 2,290 inpatients of Army Air Force Medical Manual had otitis externa.[3,9]

Raza *et al.* in ENT Polyclinic of Singleton Wales Hospital found almost 10% of the whole population had ever suffered from ADOE in their life. Similar event was reported by Tierney *et al.* who found around 240 cases per year, 30% needed follow-up, and there was 1 ADOE patient out of 6 patients who visited the clinic. Pond reported that from 14,389 patients who came to Emergency Unit of Royal Victoria Eye and Ear Hospital, 20% suffered from new cases of ADOE and 44% were patients who came for reexamination for ADOE.[8,10,11,12]

The frequency of ADOE in teaching hospital in Indonesia, such as in Karyadi Hospital in 1974-1978, out of 57,289 patients there were 8.09% ADOE patients; in Dr. Soetomo Hospital in 1975-1978, out of 88,166 patients there were 8.88% ADOE patients; in Sumber Waras Hospital in 1980-1982, out of 51,540 patients there were 8.05% ADOE patients; in Dr. Sardjito Hospital in 1990, out of 21,189 patients there were 14.70% ADOE patients. In the last five years (1998-2002), the frequency of patients with ADOE in Dr. Sardjito Hospital was 8.54-12.35%.

The infection of external ear canal skin is usually caused by aerobe bacteria, such as *Pseudomonas sp., Staphylococcus aureus, Escherichia coli.*[13,14,15] Tobing conducted a study on 50 patients of ADOE, and culture showed that the most common bacteria was Pseudomonas (48%), followed by Proteus (18%), Coliform (16%), Klebsiella (10%), and Staphylococcus (10%). This is consistent with the study by Slack who found

that the most common bacteria was Pseudomonas, followed by Proteus and Coliform, while yeast was rare.[16,17,18]

Until recently, the management of ADOE patients is variable among experts; drugs used in the treatment are also variable. Zainuddin studied the use of 10% chloramphenicol tampon and ear drop in ADOE patients, and found that in 73 subjects of ADOE patients, the use of tampon gave 89.48% recovery rate compared with the use of ear drop (76.47%), with average recurrence rate of 31.0 days in tampon group compared to 5.08 days in ear drop group.[19]

Antara studied the use of chloramphenicol, acetate acid, and boric acid antiseptics, given with tampon, on 103 ADOE patients, and found that there was no significant difference between the three drugs. The recovery rate in chloramphenicol group was 91%, in acetic acid group was 88%, and in boric acid group was 91%, with the average recovery duration of 3 days.[20]

Other research by Pond on the use of Sofradex® tampon compared with Soframycin® ear drop in 94 ADOE patients found that the recovery rate in tampon group was 70%, while in ear drop group was 64%.[11] Yaniv *et al.* compared the use of powder containing antibiotics, steroid, and antifungal (oxytetracyline, polymyxin B sulphate, nystatin, and dexamethasone) and Dex-Otic® ear drop in 67 ADOE patients, and found that recurrence occurred in average of 7 days with recovery rate of 74% in powder group and 40% in ear drop group.[12]

The use of topical antibiotics has to be cautious because of allergic reaction and microorganism resistance. Long use of antibiotics may cause fungal superinfection.[2]

In several big hospitals, the use of Burowi tampon as the first line treatment on ADOE patients gives satisfactory result. Burowi solution is an astringent, which absorbs water from tissue, causing the tissue constriction. Burowi solution has small antiseptic effect and not long-lasting.

Simple and cheap treatment like Rivanol® antiseptic is seldom used for ADOE, whereas it is available in Puskesmas and moreover Rivanol has long-lasting effect. An *in vitro* study by Masroh showed that Rivanol® solution was effective (98.42%) as antiseptic for *Pseudomonas aeruginosa* in the concentration of 0.01.[21] Rivanol® solution was active in alkaline pH by binding bacterial anion with Rivanol® cation to form an undissociated and stable salt, it is also effective as antibacterial.[21,22]

The effectivity of this drug in acute diffuse otitis externa has not been studied yet. Therefore, a study on the effectivity of this drug will be done in the treatment of ADOE. The objective of this study was to find out the difference of the effectivity of Rivanol® tampon and Burowi tampon in the treatment of ADOE.

METHOD

This was a randomized single-blind controlled trial, which compared 2 types of drugs, i.e. Rivanol® and Burowi. The first group was given Rivanol® and the second group was given Burowi tampon. The recovery rate and variables that may affect the recovery rate were analyzed.

The subjects were ADOE patients in inpatient clinic of ENT Department of Dr. Sardjito Hospital who met the inclusion and exclusion criteria. Block randomization was conducted to balance the distribution of variable characteristics in the treatment and control groups.

Inclusion criteria were: 1) edema, hyperemia, laceration, and otorrhea in external ear canal, while the tympanic membrane was still intact, pain was felt when the tragus was pressed or the auricula was moved, 2) age of 6 years old or more, 3) had not received any local or systemic antibiotics, analgetics, and antiinflammatory drugs in the last 2 weeks, 4) not allergic to Rivanol® and Burowi, 5) agreed to join the study after reading informed consent.

Exclusion criteria were: 1) perforated tympanic membrane, 2) total edema in external ear canal, so that the antiseptic tampon could not be applied, 3) had diabetes mellitus, 4) KOH test showed positive of yeast.

Ear canal of the subject was cleaned from debris and secretion. The researcher explained to the subjects about the procedure of the research, the drugs and their doses, when the evaluation would be conducted, and what will be observed until the end of the study (day 5), and the side effect of the drugs.

Subjects were given ear drop applied to tampon, which in turn was applied into ear canal. Drug was given 3 times 3 drops daily. First evaluation was conducted on day 3, and the last evaluation was conducted on day 5.

Statistical analysis used was X^2 test, Fisher's exact test, Mantel-Haenzel X^2 test, logistic regression analysis, and t test. Cost-effectiveness of each drug was calculated.

RESULTS AND DISCUSSION

Sixty eight out of 75 ADOE patients met the inclusion criteria, and the remaining 7 were excluded from the study complete the program, two subjects were from Burowi group, and 1 from Rivanol® group.

The youngest subject was 7 years old, while the oldest was 60 years old. The average age was 30.7 years old. TABLE 1 showed distribution and characteristics of research subjects.

TABLE 1. Characteristics of research subjects

	Rivanol® n (%)	Burowi n (%)	p value
Age (yrs old)			
• 5 - 14	1 (1.5)	2 (3.1)	
• 15 - 24	15 (23.1)	9 (13.8)	
• 25 - 34	9 (13.8)	9 (13.8)	0.697
• 35 – 44	3 (4.6)	6 (9.2)	
• 45 – 54	3 (4.6)	3 (4.6)	
• > 55	2 (3.1)	3 (4.6)	
Gender			
• Male	16 (24.6)	16 (24.6)	0.550
• Female	17 (26.2)	16 (24.6)	
Educational level			
• Elementary school	3 (4.6)	9 (13.8)	
• Junior high school	3 (4.6)	2 (3.1)	
• Senior high school	19 (29.2)	16 (24.6)	0.354
• Academy	1 (1.5)	-	
• Graduate	6 (9.2)	5 (7.7)	
• Postgraduate	1 (1.5)	-	
Employment			
• Unemployed	3 (4.6)	4 (6.2)	
• Private sector	12 (18.5)	11 (16.9)	0.914
• Student	11 (16.9)	9 (13.8)	
• Public sector	4 (6.2)	6 (9.2)	
• Housewife	3 (4.6)	2 (3.1)	
Instrument used to scratch the ear canal	-	2 (3.1)	
• Finger	25 (38.5)	26 (40.0)	
• Cotton bud	6 (9.2)	1 (1.5)	
• Safety pin	-	1 (1.5)	0.199
• Hairpin	-	1 (1.5)	
• Feather	1 (1.5)	1 (1.5)	
• Safety match	1 (1.5)	-	
• Did not scratch	-	-	
Trigger			
• Taking a bath	-	1 (1.5)	
• Washing hair	2 (3.1)	-	0.261
• Scratch the ear canal	30 (46.2)	31 (47.7)	
• Unknown	1 (1.5)	-	

There were no statistical significant differences in terms of subject characteristics based on age, gender, educational level, employment, trigger, instrument used to scratch the ear canal, and the affected ear side.

First evaluation of recovery on day 3 showed that 20 subjects (30.8%) in Rivanol® group were cured and 13 subjects (20.0%) were not cured yet, while in Burowi group, there were 12 subjects (18.5%) who were cured and 20 subjects (30.8%) who were not cured yet. The difference was not statistically significant (X^2, p 0.053). Second evaluation at day 5 showed that 29 subjects (44.6%) in Rivanol® group were cured and 4 subjects (6.2%) were not cured yet, while in Burowi group, there were 20 subjects (30.8%) who were cured and 12 subjects (18.5%) who were not cured yet. The difference was statistically significant (X^2, $p < 0.05$) (TABLE 2).

TABLE 2. First and second clinical evaluation of treatment result in both treatment groups

Evaluation	Recovery	Rivanol® N (%)	Burowi N (%)	p value
1	Cured	20 (30.8)	12 (18.5)	0.053
	Not cured	13 (20.0)	20(30.8)	
2	Cured	29 (44.6)	20 (30.8)	0.018
	Not cured	4 (6.2)	12 (18.5)	

Acute diffuse otitis externa is superficial skin infection with treatment principle of cleaning the discharge/debris regularly and giving topical drugs. Ear tampon use may directly inhibit and stop the growth of pathogenic microorganism in the ear canal by pressing on canal skin surface and lengthy drug contact. Arndt[23] suggested that the recovery depends on the duration of drug contact with ear canal skin surface, compared with ear drop use that will be decreased in absorption 15-60 minutes after application, so that ear tampon use is clearly more beneficial.

The other function of tampon use is to inhibit patient from manipulating the affected ear, in order to accelerate healing. Histologically, thin ear canal skin may facilitate drug diffusion, not only because of the chemical effect, but also mechanically caused by the pressure from ear tampon.

The result of treatment on day 3 showed 12.3% difference between recovery of the two groups, but the difference was not statistically significant. This is consistent with a study by Suharyono.[24] Based on a study by Basjrah and Zuraidah, the recovery rate of Burowi was between 50-68%, and the study showed 49.3% cure rate.[25,26] An *in vitro* study by Masroh showed 98.42% efficacy of Rivanol® solution as antiseptic for acute diffuse otitis externa with 75.4% recovery rate. From this study, there was 26.1% difference between cure rates compared to Rivanol® group.[21]

Rivanol gave best result because it was an antiseptic for gram positive and negative bacteria, and also yeast. Aside of the attachment between Rivanol® cation with bacterial anion, Rivanol® also attaches the nucleic acid of bacteria or yeast, inhibiting the DNA synthesis of bacteria and yeast, causing the change in mutation in protein synthesis reference.

Average recovery day of Rivanol® group was 4.1 days, while in Burowi group was 4.9 days, and it was statistically different. This result showed a significant difference between recovery day in both treatment groups where Rivanol® caused healing faster than Burowi (TABLE 3).

TABLE 3. Average recovery day in each treatment group

Group	Average recovery day	p value
Rivanol®	4.12	0.046
Burowi	4.90	

Result of the study by Zainuddin showed healing time for ADOE was in average of 6 days, it was different with the result of the study by Antara, which was 3.4-3.7 days. The result was almost

similar with the study by Basjrah which showed an average of 3.39 days with Burowi.[19,20,25,26] In this study, Rivanol® tampon gave faster recovery, because Rivanol® as antiseptic acted in alkaline condition, and was a wide-spectrum antiseptic, so that it was effective to be used in ADOE patients. Burowi exhibits an astringent effect by absorbing water from ear canal and does not inhibit the growth of micro-organism directly.

The side effect in Rivanol® group occurred in 1 (1.5%) subject at the end of the study, in the form of dampness and soggy feeling in the ear, but they could be tolerated by the patient. In Burowi group, the side effect was stinging sensation in 2 (3.1%) subjects, but the symptom was mild and could be tolerated by the patients.

Cost calculation revealed that to cure an ADOE patient with Rivanol® tampon needed only Rp 1000,-

CONCLUSION

The use of Rivanol® tampon was clinically effective and cost-effective compared to Burowi tampon for acute diffuse external otitis patients.

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