Variability Of Ear Drops In Normal Population: An Accurate Delivery Device Required

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Citation

M De, P McDonald, R Vaughan-Jones. *Variability Of Ear Drops In Normal Population: An Accurate Delivery Device Required*. The Internet Journal of Otorhinolaryngology. 2006 Volume 6 Number 1.

Abstract

Otolaryngologists and general practitioners commonly prescribe eardrops for various ear conditions. Compliance has not been studied, but is generally thought to be poor.

Method:

Our aim was to demonstrate the variability of dosage amongst individuals. To ascertain, if the handedness or sex, made a difference to aural drop application. Twenty asymptomatic right-handed staff volunteers took part in the study. All were aware of the potential side effects of Betamethasone and agreed to be accurate in the application of drops. We also obtained ethical approval of the study. All volunteers had otoscopic examination before the instillation of drops. They were asked to apply four Betamethosone eardrops to each ear. Compliance was measured using a pharmacy weighing scale.

Results:

There was significant intra volunteer variability (Range 1.64 to 9.96). The standard weight of Betamethasone drops was 0.025 grams. Statistical analysis shows males were instilling on average 4.5 drops per ear and females were instilling 1.8 drops per ear. A statistically significant difference was found between sexes (p=0.003). There was no difference in dosage between hands (p=0.229). Statistical analysis shows no correlation between the weight of the bottle and the number of drops applied. (Spearman rho = 0.35, p=0.406).

Conclusion:

The above result shows significant variability of dosage amongst volunteers and between sexes. We therefore conclude that there is need for delivery device for an objective dosage administration.

INTRODUCTION

Topical medications are widely used in the treatment of otological disease and are traditionally administered in the form of eardrops. This is usually delivered via a dropper of nozzle. Treatment regimes advocate a specific number of drops for a short period. There have been concerns regarding the delivery of drops and excessive use of corticosteroids [1,2]. The aerosol drug delivery system can overcome the variability of eardrop distribution and give better coverage of external ear canal [3]. In order to investigate the variability claim we have conducted this simple study.

METHODS

This is a prospective study to analyse the accuracy of drop application amongst individuals. We selected ten male and ten female asymptomatic staff volunteers, all were right hand dominant. Each volunteer had a routine otoscopic examination, which was found to be normal. All were aware of the possible side effects of Betnesol and each consented to the study. They were asked to apply four drops of Betnesol to each ear, using the right hand for the right ear and left hand for the left ear. The accuracy was measured using a digital pharmacy weighing scale, accurate up to three decimal points.

We assessed:

- Variability of dosage amongst volunteers

- Did handedness made a difference
- Was gender a cause for variability
- Was there any relationship between the weight of the bottle and the number of drops applied

RESULTS

The results were analysed using nonparametric tests in accordance with distribution (Figure1). The median weight difference was 0.09 with median weight drop difference of 3.42 per ear, taking whole sample (male and female together). There was significant intra-volunteer variability (Range 1.64 to 9.96) per ear per volunteer (Figure1). The males were instilling more drops (median weight difference = 0.112 and median drop = 4.5). The females were instilling fewer drops (median weight difference = 0.045 and median drop was = 1.8).

There was significant difference between the equivalent drops between male and female. The median equivalent drop in males was 4.5 compared to 1.8 in case females (Mann Whitney U Test, W = 301.00, Z = -2.949, P = 0.003). There was difference with respect to weight, male with 0.112 to female weight 0.045. (Mann Whitney U Test, W = 306.000, Z = -2.814, P = 0.005)

The median drop for right hand was 4.1 compared to left hand with 3.06. However the statistical test shows no difference between hands (Mann Whitney U test, W = 365.5, Z = 1.204, P = 0.229).

No significant correlation was found between the weight of the bottle and the number of drops applied. (Spearmans rho = 0.135, P = 0.406).

Figure 1

		LEFT			RIGHT		
Initial	Wt(g)	15.216	difference	Equ drops	15.208	difference	Equ drops
Sub1	4 drops	15.175	0.041	1.64	14.718	0.049	1.96
2	8	14.980	0.195	7.8	14.548	0.170	6.80
3	12	14.870	0.110	4.4	14.411	0.137	5.48
4	16	14.756	0.114	4.56	14.291	0.120	4.80
5	20	14.677	0.079	3.16	14.189	0.102	4.08
6	24	13.747	0.093	3.72	14.072	0.117	4.68
7	28	13.591	0.156	6.24	13.936	0.136	5.44
8	32	13.469	0.122	4.88	13.853	0.083	3.32
9	36	13.381	0.088	3.52	13.604	0.249	9.96
10	40	13.307	0.074	2.96	13.547	0.057	2.28

Figure 2

Women

		LEFT			RIGHT		
Initial	Wt (g)	15.232	difference	Equ drops	15.240	difference	Equ drops
Sub1	4 drops	15.216	0.016	0.64	15.208	0.032	1.28
2	8	15.206	0.010	0.40	15.170	0.038	1.52
3	12	14.326	0.088	3.52	15.121	0.049	1.96
4	16	14.231	0.095	3.80	14.989	0.132	5.28
5	20	14.198	0.033	1.32	14.949	0.040	1.60
6	24	14.136	0.062	2.48	14.751	0.198	7.92
7	28	14.117	0.019	0.76	14.648	0.103	4.12
8	32	13.977	0.140	5.60	14.583	0.065	2.60
9	36	13.937	0.040	1.60	14.557	0.026	1.04
10	40	13.909	0.028	1.12	14.415	0.142	5.68

DISCUSSION

This study is based on the objective assessment of the accuracy of patient self-medication with ear drops. Studies have shown that the distribution of eardrops is variable in a normal population [2]. There are also several studies measuring the accuracy of nasal drop application [1,4].

Our result shows there was significant variability amongst volunteers. Range was 1.64 to 9.6 drops per ear per volunteer. The result shows males were instilling more drops compared to females (Median equivalent drops in males was 4.5 and females 1.8). Results show no difference between right and left hand, however there was a trend towards right hand. There was no correlation between the weight of the bottle and the number of drops applied.

Betnesol is one of the commonly used eardrops. The authors feel there is a necessity of using special delivery devices like droppers, capsules or sprays. This would minimise the chance of variability. We feel there are some limitations in our study. The sample size was small. We obtained only one observation per hand per volunteer.

CONCLUSION

The above result shows significant variability of dosage amongst volunteers and between sexes. We therefore conclude that there is need for delivery device for an objective dosage administration.

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