THE RATIONAL THERAPY OF EAR INFECTIONS

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Introduction

"The problems of deafness are deeper and more complex, if not more important than those of blindness. Deafness is a much worse misfortune, for it means the loss of the most vital stimulus - the sound of voice - that brings language, sets thoughts astir and keeps us in the intellectual company of man" (Helen Keller 1880 - 1968)

Two studies were carried out concerning ear infections at St. Luke's Hospital in Malta, between July and November, 1991.

Aims

Survey 1

This survey dealt with ear infections in general. Its aims were to find the common infections, patients' age distribution, presenting signs and symptoms, diagnostic techniques used to identify the infections, pathogens and their sensitivity and resistance to antibiotics and drug treatment given.

Survey 2

This survey concerned the potentially lethal ear infection Malignant Otitis Externa (MOE). The aims of this survey were to find the patients' age distribution, common presenting signs and symptoms, diagnostic techniques used to identify the infection, pathogens, any correlation between the severity of the disease and control of diabetes mellitus, treatment given and its total cost. The latter includes the cost of drugs used to treat M.O.E., any other drugs required to treat any other conditions suffered by the patient, for example anti-diabetics, antihypertensives, any operations performed and hospital stay.

Methodology

Survey 1

Analysis of patient records over 3 months was performed at the Ear, Nose and Throat clinic of the outpatients' department of St. Luke's Hospital and data collected.

Survey 2

This was conducted on patients with M.O.E. who were admitted to the E.N.T. ward. For 5 months, patients' medical records were reviewed on admission and during their stay.

A list of the Government's tender prices of the drugs used was obtained from the Government's Medical Stores. The daily cost of a hospital stay and operations' cost were obtained from the Department of Health.

Results

Survey 1

Types of ear infections

This survey was conducted on 67 patients, 38 males and 29 females. The age range was 4 - 77 years, the mean age being 38 years. See Table 1.

Table 1: Types of ear infections, their percentage incidence and their most common presenting sign or symptom

Ear Infection	Incidence	Most common presenting sign or symptom
Chronic suppurative otitis media (CSOM)	37.3	Perforated tympanic membrane
Chronic diffuse otitis externa (COE)	28.3	Discharge
Otitis media with effusion (OME)	13.4	Fluid in middle ear
Acute diffuse otitis externa (AOE)	11.9	Otalgia
Otomycosis	11.9	Discharge
Acute suppurative otitis media (ASOM)	11.9	Perforated tympanic membrane
Furunculosis	2.99	Otalgia, furuncle
Adhesive otitis media	2.99	Fibrous exudate, hearing loss

Diagnosis was achieved by means of physical examination of the ear, tuning fork tests, pure tone audiometry, culture and sensitivity tests, histology, X-rays, computerised tomographic (CT) scans and surgery.

No culture and sensitivity tests were recorded for furunculosis, AOE, ASOM, OME and adhesive otitis media. Otomycosis was mainly caused by fungi, which were not *Candida albicans*. The most common pathogen of both COE and CSOM was *Pseudomonas aeruginosa*.

Among the most commonly used topical preparations were Dexamethasone, hydrocortisone, neomycin, sulphate and polymyxin B. Some of the most commonly administered systemic antibiotics were amoxycillin plus clavulanic acid, ampicillin and pseudoephedrine HCl.

Survey 2

Malignant Otitis Externa

This survey was conducted on 9 patients, 6 males and 3 females, 90% of yearly cases, mean age 68.64 (age range 52 - 92 years). All patients were diabetics. The presenting signs and symptoms were recorded.

Diagnostic techniques used to identify malignant otitis externa were the same as those used to diagnose other ear infections.

The types of organisms found in the affected ear were *Pseudomonas aeruginosa, Staphylococcus albus, Proteus,* Gram-negative bacilli, *Candida albicans* and yeasts. No correlation was found between blood glucose level and the severity of the disease.

The types of antibiotics used were the aminoglycosides, cephalosporins, the penicillins, erythromycin, sulphadiazine, metronidazole and rifampicin, giving a total of eleven combinations. Table 2 shows the different combinations given to each patient and the total cost of therapy of each patient.

Three different therapies-monotherapy with ceftazidime (CEFT), the ciprofloxacin-rifampicin (CIPR-RIF) combination and the ceftazidime-ciprofloxacin-rifampicin (CEFT-CIPR-RIF) combination were compared with the other drug combination used as treatment of M.E.O. Such therapies were chosen since they include the newest drugs found to be

Table 2: The drug therapy and total cost for all the 9 patients with Malignant Otitis Externa

Patient	Drug Combination	Length of hospital stay /days
A*	Ceftazidime erythromycin gentamicin metronidazole	52
	Ceftazidime sulphadiazine	21
	Ceftazidime cephalothin gentamicin metronidazole sulphadiazine	72
	Ciprofloxacin rifampicin	23
B	Ceftazidime ciprofloxacin rifampicin	15
C*	Carbenicillin gentamicin metronidazole	57
	Amikacin carbenicillin	97
D	Azlocillin Ceftazidime	49
E	Amikacin Ampicillin/cloxacillin Ceftazidime Gentamicin Metronidazole	81
F	Ceftazidime Gentamicin	34
G	Ceftazidime ciprofloxacin rifampicin	72
H*	Azlocillin ceftazidime	43

*Patients A, C and H have more than one drug combination because they were admitted more than once to hospital.

Table 3

Patient	Cost of drugs for treatment of malignant otitis externa /Lm	Cost of other drugs/Lm	Cost of	Cost of operations stay/Lm	Total cost hospital/Lm
A*	282.39	55.04	120	3120	3577.43
	423.36	27.25		1260	1710.61
	1043.17	67.11		4320	5430.28
	65.09	7.76		1380	1452.85
					12171.17
B	53.39	3.26	60	900	**1016.65**
C*	304.75	134.66	60	3420	3919.41
	347.94	169.21		5820	6337.15
					10256.56
D	709.97	31.10		2940	**3681.07**
E	974.33	77.78		4860	**5912.11**
F	495.77	14.83	60	2040	**2610.60**
G	605.48	74.76		4320	**5000.24**
H*	429.49	24.03	120	2580	3153.52
	208.45	11.97		840	1060.42
					4213.94
I	230.88	13.39	60	1560	**1864.27**
					46726.61

*Patients A, C and H have more than on total cost of therapy because they were admitted more than once to hospital. All prices in Maltese Lira.

Patient	Total cost/saving if ceft. used/LM		Total cost/saving if cipr. rif. combination used/LM		Total cost/saving if ceft. cipr. rif. combination used/LM	
A	7377.78	4792.95	5983.75	6186.98	12171.86	-1.13*
B	1852.42	308.32	1506.09	1556.93	1016.65	/
C	3748.54	6508.51	3044.64	7217.41	6187.06	4069.99
D	1813.98	762.94	1465.53	1110.64	3012.18	-431.58*
E	1815.85	4095.55	1467.18	4444.22	3015.33	3229.15
F	1862.22	747.65	1515.12	1094.75	3052.27	-1102.40*
G	1835.18	308.32	1484.28	1556.93	5018.98	/
H	3728.50	1525.88	2221.28	3033.84	6111.42	-863.16*
I	1864.27	/	1516.94	347.33	3055.74	-1191.47*
	25898.74	19050.12	21017.37	25731.47	42641.49	3709.40

*The minus sign indicates that losses would have been involved if one of the three particular regimens were used in that case.

Table 4: Total cost of treatment and saving of all the 9 patients with malignant otitis externa if the three particular regimens were used

effective in the treatment of the infection. Table 4 shows the total cost of treatment and total savings for all the 9 patients, for each individual when treated with the three particular regimens.

Thus the total savings that would have been involved are:

1) Ceftazidime only: Lm19,050.12, i.e. 40.8% of the actual total cost of treatment of all the 9 patients (Lm46,726.61)
2) Ciprofloxacin and rifampicin: Lm25,731.47, i.e. 55.1%.
3) Ceftazidime, ciprofloxacin and rifampicin: Lm3,709.40, i.e. 7.94%

Alternatively, the savings associated with each patient would have been 4.5% if ceftazidime was used, 6.1% if ciprofloxacin and rifampicin was used and 0.9% if ceftazidime-ciprofloxacin-rifampicin combination was used.

Discussion and Conclusions

Survey 1: Cases registered showed that ear infections can occur in all age groups without preference. The most common infections were found to be CSOM and COE. Had diffuse otitis externa not been divided into acute and chronic stages, the percentage incidence of this infection would be grater than that of CSOM.

Some presenting signs and symptoms can be similar for the different ear infections. However, other signs and symptoms are specific to a particular infection. Thus diagnostic techniques are very important for thorough examination of the ear, identification of the signs and symptoms and hence the particular infection and correct treatment.

The most common pathogen of both COE and CSOM was *Pseudomonas aeruginosa*. This was also reported in a previous study (Yagi, 1990).

Various drugs were used in the treatment of ear infections. The antibiotics were prescribed topically, namely in the form of ear drops and creams, the former being much more common, and systemically, namely periorally, intramuscularly and intravenously, periorally being the most common. Topical steroids were also prescribed in combination with topical antibiotics. In fact, the most common topical preparations used wre hydrocortisone, neomycin sulphate, polymyxin B sulphate plus tolnaftate drops and dexamethasone, framycetin sulphate and

gramicidin drops. The most common systemic antibiotics were amoxycillin plus clavulanic acid, ampicillin and erythromycin.

Survey 2: Malignant otitis externa, also termed necrotising otitis externa, is both an important and interesting clinical entity. It is a potentially lethal disease affecting patients who are usually elderly and diabetic in whom *Pseudomonas aeruginosa* causes an osteomyelitis of the skull base, using the external ear as a port of entry (Sade et al, 1989). In fact all patients in the study were elderly diabetics and the most common pathogen was *Ps. aeruginosa.* The microangiopathy of diabetes, specifically microangiopathy of the skin of the external auditory meatus, results in local tissue perfusion and creates an environment well suited for invasion by Ps. aeruginosa (Doroghazi et al., 1981).

Blood glucose level was not found to be an indication of the severity of the disease. This was also reported in a previous study (Doroghazi et al,, 1981).

Prompt diagnosis and correct treatment are very important to avoid extension of the inflammation and neurological complications. Thus diagnostic techniques are essential for correct diagnosis.

Various combinations of antibiotics have been used in Malta throughout the years, in accordance with the current therapy used in other countries for the disease in question.

In the present study, it was found that monotherapy with ceftazidime, the ciprofloxacin-rifampicin combination and the ceftazidime-ciprofloxacin-rifampicin combination are all cost-effective because the total cost of therapy is cheaper than that of the other therapies and the drugs are safer than the others. The most cost-effective therapy was found to be the ciprofloxacin-rifampicin combination, ciprofloxacin being given 500-750mg and rifampicin 600mg, both twice daily and periorally. Using the ciprofloxacin-rifampicin combination, the disease can be trated without the patient being admitted to hospital or at least for a short period of time for observation. The results given previously are theoretical and could be subject to some change.

Malignant otitis externa seems to be more common in Malta than in other countries. This is probably due to the fact that diabetes has a relativley high incidence in Malta (9.8%) compared to other countries (5.2%)

(Papoz, 1990) and that Malta has a hot and humid climate, both factors being prognostic for M.O.E.

The pharmacist has a role in the treatment of ear infections both in the community and at hospital. He/she can give advice on the proper use of ear drops (e.g. 2 or 3 drops should be placed in the affected ear with the head tilted on the other side and kept thus for five minutes to ensure adequate contact of the active ingredients with the infected areas) as this is mandatory for effective treatment of the infection. At hospital, the pharmacist can ensure that the patients are compliant, that is, they are taking the prescribed drugs appropriately. He/she can also monitor the drug blood levels of patients to whom ototoxic and/or nephrotoxic drugs such as the aminoglycosides are administered. Thus the pharmacist can be an important member of the health care team for the treatment of patients suffering from ear infections.

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