

## INTISARI

Otitis media supuratif kronik (OMSK) adalah infeksi kronik telinga tengah disertai perforasi membrana timpani dengan sekret yang keluar terus menerus atau hilang timbul. Insidensi Otitis Media Supuratif Kronika Benigna Aktif (OMSKBA) di negara berkembang 5% - 10%, sedangkan di negara maju 0,5% - 2%. Terdapat hubungan yang bermakna antara fungsi drainase tuba auditoria terhadap kesembuhan OMSKBA. Proses patologi di telinga tengah akan menyebabkan meningkatnya jumlah sel-sel goblet dan akan terjadi akumulasi sekret di kavum timpani.

Penelitian ini bertujuan untuk menentukan hasil guna kombinasi karbosistein dan terapi standar dibanding terapi standar saja terhadap kesembuhan OMSKBA.

Hipotesis penelitian ini adalah kombinasi karbosistein dan kloramfenikol tetes telinga lebih berhasil guna dibanding terapi standar saja

Penelitian ini menggunakan rancangan uji klinis acak terkontrol buta ganda (*double blind Randomized Controlled Trial*). Tempat penelitian di poliklinik THT RS Dr.Sardjito Yogyakarta bulan Januari 2001 sampai dengan Desember 2001. Hasil terapi dievaluasi pada hari ke 14. Efek samping pemakaian obat dicatat.

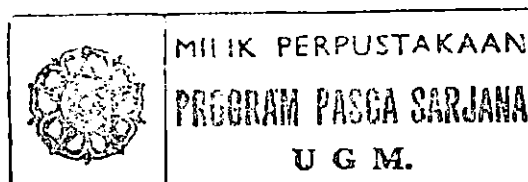
Pengukuran hasil: Sembuh (sekret telinga negatif/kering) dan tidak sembuh (sekret telinga menetap atau bertambah).

Analisis statistik dengan statistik diskriptif, uji Z, tes Mantel-Haenszel, regresi logistik dan *cost effectiveness*.

Hasil : Sebanyak 104 orang subyek dikelompokkan menjadi dua group perlakuan secara randomisasi sederhana. 1 (1%) orang subyek dinyatakan drop-out, jumlah subyek menjadi 103, 54 subyek pada kelompok karbosistein dan 49 subyek pada kelompok kontrol. Subyek yang dinyatakan sembuh pada kelompok karbosistein adalah 45 (83,3%), kelompok kontrol 31(63,3%). Perbedaan angka kesembuhan pada kedua kelompok tersebut bermakna secara statistik dengan  $p=0,02$ ,  $RR=1,78$ , 95%  $CI:1.01-3.13$

Kesimpulan dari penelitian ini adalah karbosistein dan kloramfenikol tetes telinga lebih berhasil guna dibanding terapi standar saja.

**Kata kunci :** OMSKBA, drainase, karbosistein, hasil guna ,uji klinis acak terkontrol



## ABSTRACT

Chronic suppurative middle ear otitis is a chronic infection in the middle ear accompanied by tympanic membrane perforation with continuous or intermittent discharge. The incidence of BCSOM in developing country is 5%-10%, and in developed country is 0,5%-2%. There was a significant correlation between drainage function of auditory tube with level of cure of BCSOM. Pathological process in the middle ear causes increasing of goblet cells number and discharge accumulation in the tympanic cavity.

**The aim of this study :** to determine the effectiveness of carbocystein peroral combined with standart therapy, as compared to the standart therapy as single therapy on the cure of BCSOM in Yogyakarta.

**Hypothesis :** combination of carbocystein and chloramphenicol ed is more effective compared to standart therapy.

This study was a double blind Randomized Controlled Trial. The study taken place at the ENT Departement Clinic, Dr. Sardjito Hospital, Yogyakarta in January 2001 – December 2001.

**Main outcome measures :** Cured (dried or improved ear) and not cured (wet tympanic cavity). Chi-square test, t- test, Mantel-Haenszel procedure were used to identify the independent variable .

**Result :** All of 104 participants were randomly allocated into Carbosistein group and control group. From all participants, 1 patiens were dropped-out of 104 cases, the number of carbocysteine group were 54 persons, control group were 49 persons. Carbosisteine's cured rate was 83.3% and control goup was 63,3%. The difference of cured rate from these two groups was statistically significant ( $p=0.02$ ,RR: 1,78, 95% CI: 1,01-3,13).

**Conclusion:** carbocysteine combined with chloramphenicol ed is more effective and more cost effective than standart therapy for treating ABtCOM. There is no side effect in carbocysteine samples group.

**Keywords :** *BCSOM, drainage, carbocystein, effectiveness, randomized controlled trial, double blind.*

