

SNHL in Patients with IBD & its Predictors

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ABSTRACT

Introduction: India's National Health Policy 2018 (NHP-2018) has its goal fully aligned with the concept of Universal health coverage. The Ayushman Bharat Program announced in the Union budget 2018-19 of the Government of India, aims to carry NHP-2018 proposals forward. Along with Ayushman Bharat there are other state run health insurance schemes as well which are catering to the needs of the people. Government sponsored health insurance schemes have received an unprecedented public, political and media attention. This article studies the trends in utilization of healthcare services under government sponsored health insurance schemes in select cities of Maharashtra.

Aim & Objectives: To study the trends in the awareness and utilization of inpatient healthcare Services under Government Sponsored Health insurance Schemes in Select Cities of Maharashtra namely Pune, Mumbai and Nagpur

Findings: Utilization trends in three select cities of Maharashtra have been studied. The sources of awareness regarding such schemes were hospitals. The study also highlights utilization specialty health care services amongst all age groups in selected cities.

Conclusion: Utilization trends suggest the need of government sponsored health insurance schemes. The schemes have been found to be beneficial for all the age group

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INTRODUCTION

Inflammatory bowel disease (IBD) is an immune-mediated disorder that leads to inflammation and ulceration of the gastrointestinal tract. The degree and site of involvement are related to disease subtypes, the most common of which are Crohn's disease (CD), ulcerative colitis (UC), and Inflammatory bowel disease undetermined (IBDU). In addition to gastrointestinal tract involvement, extra-intestinal manifestations (EIMs) are common complications in patients with IBD. EIMs occur in 25%-40% of IBD patients and affect various organs, such as the skin, joints, blood vessels, eyes, kidneys, and biliary tract (Levine and Burakoff, 2011). Based on recent findings, IBD has also been linked to several auditory disorders (Zois et al., 2008), commonly presenting as symptomatic or asymptomatic sensorineural hearing loss (SNHL). Owing to the presumed immunological basis of IBD, there is an implication that the possible association with the ear may be immune-mediated (Mathews and Rao SKumar, 2003).

Predictors of auditory involvement in IBD are yet to be determined conclusively, but older age has been identified as an essential risk factor in a recent study (Akbayir et al., 2009). The location and severity of the disease have been consistently associated with the development of SNHL, as are some types of medication and other EIMs. Other established risk factors include family history, exposure to ototoxic drugs, and head trauma, as suggested by previous studies (Akbayir et al., 2005; Bachmeyer et al., 1998; Jin YNi, 2009; Kalyoncu et al., 2010; Kariya et al., 2008, Karmody et al., 2009). The present study aimed to estimate the prevalence of SNHL in a cohort of Saudi Arabian patients diagnosed with IBD and to identify a possible association between disease activity and SNHL.

MATERIALS AND METHODS

A prospective observational research design included all IBD patients presenting at the gastroenterology clinic at King Abdulaziz University Hospital (KAUH). Patients who provided written informed consent

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for participation were screened for eligibility. The inclusion criteria were age >12 years and an established IBD presence according to typical clinical, histological, and radiological criteria. Patients with SNHL following the diagnosis of Ménière's disease were excluded (Figure 1). Several types of data were recorded, including demographic characteristics (e.g., age and sex), duration, phenotype (based on the Montreal classification), extent and location of disease, history of smoking and abdominal resection, medication (past and current), use of steroids, diet-related restrictions, marital status, and clinical symptoms. Clinical analysis was conducted to examine complete blood count (CBC), C-reactive protein (CRP), electrolytes, baseline kidney function, liver enzymes, faecal calprotectin, and blood sugar. At the evaluation time, up-to-date patient endoscopic reports were reviewed to classify disease activity according to the presence or absence of frank ulcerations in CD patients and the Mayo endoscopic score for UC patients. A colonoscopy procedure was performed if the most recent endoscopic evaluation was performed more than three months before the study commencement. Disease severity was assessed using the Harvey-Bradshaw index (HBI) for CD patients and the partial Mayo score for patients with UC (Kariya et al.,2008, Karmody et al.,2009).

Hearing Assessment

Patients who met the inclusion criteria were referred to the otolaryngology department for hearing assessment, otoscopy, tympanometry, and pure tone audiometry. SNHL was defined as hearing loss with 25 decibels (dB) threshold level. A categorisation of SNHL was set as "mild" (26-40 dB hearing loss), "moderate" (41-55 dB hearing loss), "moderately severe" (56-70 dB hearing loss), "severe" (71-90 dB hearing loss), or "profound" (>91 dB hearing loss).

Study Outcomes

This prospective observational study investigated the relationship between IBD and SNHL. The primary outcome was to estimate the prevalence of SNHL, and the secondary outcome was to identify the clinical predictors of SNHL.

Statistical Analysis and Sample Size Calculation

Descriptive statistics are presented as means (\pm standard deviations [SD]) for continuous and categorical variables. An independent *t*-test and a Mann-Whitney U test were used to

compare means, and a chi-squared test and Fisher's exact test were used to compare frequencies. The analysis was carried out using a two-tailed distribution with a statistical significance threshold of 5% and 95% confidence intervals. Stata statistical software (StataCorp, Texas, USA, version 12.0) analysed the data.

Ethical Considerations

The Research Ethics Board at King Abdulaziz University approved the study (reference #281/16), and informed consent was obtained from all patients. This study was conducted in accordance with the Declaration of Helsinki.

RESULTS

Baseline Characteristics

The cohort comprised 33 patients with IBD (22 with CD and 11 with UC). The median age was 29 years (15-62 years). Females constituted 54.5% (n=18), and 78.8% were of Saudi Arabian nationality. Among patients with CD, the most common disease location was ileocolonic (95.4%), and the most common disease behaviour was inflammatory (54.5%). Patients with UC had an equal percentage of left-sided colitis (45.5%) and pancolitis (45.5%). Most patients with CD were in clinical remission (54.4%), while 45.5% of UC patients had quiescent disease, and 45.5% had mild disease activity during the study (Table 1).

Study outcomes

Hearing assessment

In the study cohort, six (18.2%) IBD patients reported ringing, roaring, or hissing sounds in the ears, 5 (15.2%) noted trouble understanding phone conversations, 5 (15.2%) had difficulty following discussions if more than one person speaks at a time, 5 (15.2%) had received frequent complaints by others that they listened to the TV too loudly, 4 (12.1%) had trouble hearing speech above the background noise and often had to ask people to repeat themselves (Table 2). Four patients (12.1%) reported using non-steroidal anti-inflammatory drugs, and two patients (6.1%) reported using diuretics; none reported the use of aminoglycosides. A history of frequent exposure over an extended period to loud noise was found in seven patients (21.2%), and four patients (12.1%) reported a history of physical head injuries. Only two patients (6.1%) had a family history of hearing loss (Table 2).

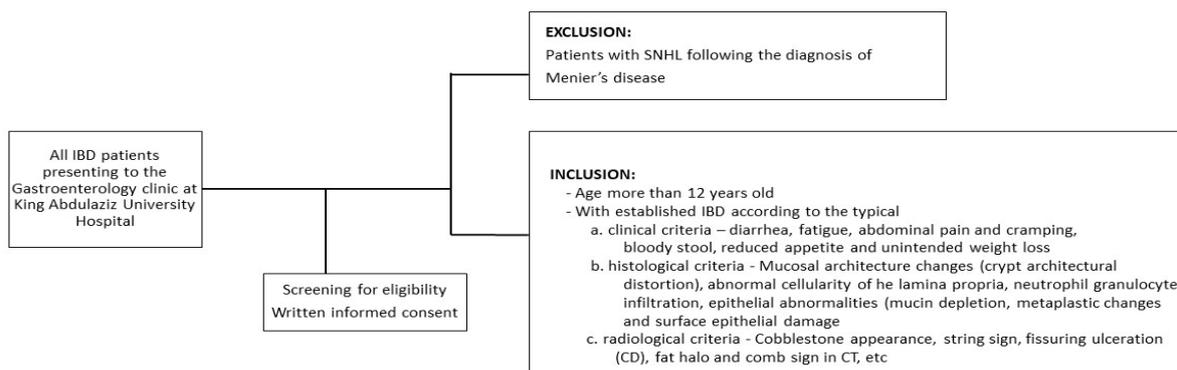


Fig. 1: Detailed study inclusion-exclusion criteria for inflammatory bowel disease patients being screened for sensorineural hearing loss in King Abdulaziz University Hospital, Jeddah, Saudi Arabia. IBD- Inflammatory Bowel Disease, SNHL- sensorineural hearing loss, CD- Crohn's disease.

Table 1: Clinico-demographic characteristics and treatment/management used for inflammatory bowel disease patients screened for sensorineural hearing loss in King Abdulaziz University Hospital, Jeddah, Saudi Arabia

Variables	N (%) or mean \pm SD
Demographics	
Age (years)	31.9 \pm 11.7
Female gender	18 (54.5)
Saudi nationality	26 (78.8)
Smoking	6 (18.2)
Clinical Characteristics	
Inflammatory Bowel Disease subtype	
Crohn's disease	22 (66.7)
Ulcerative colitis	11 (33.3)
Disease duration (months)	6.3 \pm 4.8
Disease location (Crohn's Disease)	
L1: Ileal	1 (4.5)
L2: colonic	0 (0.0)
L3: Ileocolonic	21 (95.4)
Disease behavior (Crohn's Disease)	
B1: non stricturing non penetrating	12 (54.5)
B2: stricturing	4 (18.2)
B3: penetrating	6 (27.3)
Perianal disease (Crohn's Disease)	
Disease severity (Crohn's Disease)	1 (4.5)
Clinical remission	19 (86.4)
Mild	1 (4.5)
Moderate	2 (9.1)
Disease Extension (Ulcerative Colitis)	
E1: Ulcerative proctitis	1 (9.1)
E2: Left sided colitis	5 (45.5)
E3: Pancolitis	5 (45.5)
Disease severity (Ulcerative Colitis)	
Clinical remission	5 (45.5)
Mild	5 (45.5)
Severe	1 (9.1)
Extra Intestinal Manifestations	4 (12.1)
Inflammatory Bowel Disease medications	
Mesalamine	10 (30.3)
Corticosteroids	14 (42.2)
Azathioprine	12 (36.4)
Biological therapy	11 (33.3)

Ear examination and hearing tests

Otосcopy revealed normal findings in 32 patients (97%). Right and left tympanometry was normal in 90.9% and 84.4% of patients, respectively. Right pure tone audiometry showed SNHL in 21.1% of patients and conductive hearing loss in 6.1%, while left pure tone audiometry revealed SNHL in 21.2% of patients, conductive hearing loss in 3%, and mixed in 6.1% (Table 3).

Bivariate analysis of variables in patients with or without SNHL

A bivariate analysis of related variables was performed on patients with SNHL (n=9) and patients without SNHL (n=24), showing no significant associations (Table 4).

Table 2: History of hearing difficulties, ototoxic medications, risk factors and conditions associated with hearing loss according to subtypes of Inflammatory Bowel Disease.

Item	CD (n=22)	UC (n=11)	IBD (n=33)
	N (%)	N (%)	N (%)
History of hearing difficulties			
Trouble understanding phone conversations	3 (13.6)	2 (18.2)	5 (15.2)
Trouble hearing above background news	3 (13.6)	1 (9.1)	4 (12.1)
Trouble following a conversation when more than one person speaks at once	3 (13.6)	2 (18.2)	5 (15.2)
Perception that people are not speaking clearly or mumbling	1 (4.5)	0 (0.0)	1 (3.0)
Often misunderstanding what people say and responding inappropriately	1 (4.5)	0 (0.0)	1 (3.0)
Often having to ask people to repeat themselves	3 (13.6)	1 (9.1)	4 (12.1)
Frequent complaints by others that the TV is too loud	4 (18.2)	1 (9.1)	5 (15.2)
Ringing, roaring, or hissing sounds in the ears	3 (13.6)	3 (27.3)	6 (18.2)
Ototoxic medications			
Aspirin	0 (0.0)	1 (9.1)	1 (3.0)
NSAID	2 (9.1)	2 (18.2)	4 (12.1)
Diuretics	1 (4.5)	1 (4.5)	2 (6.1)
Risk factors of hearing loss			
Exposure to loud noise for a long period of time	5 (22.7%)	2 (18.2)	7 (21.2)
Physical head injury	2 (9.1)	2 (18.2)	4 (12.1)
Family history of hearing loss	1 (4.5)	1 (9.1)	2 (6.1)
Conditions associated with hearing loss			
Viral infection of the inner ear mumps, measles	1 (4.5)	0 (0.0)	1 (3.0)
Ménière's disease	0 (0.0)	1 (9.1)	1 (3.0)
Stroke	0 (0.0)	1 (9.1)	1 (3.0)
Cardiovascular disease	1 (4.5)	0 (0.0)	1 (3.0)

CD: crohn's disease, UC: ulcerative colitis, IBD: Inflammatory Bowel Disease, NSAID: Non-steroidal anti-inflammatory drugs

DISCUSSION

This prospective observational study investigated the relationship between IBD and SNHL. The mean age of the study cohort, 31.9 \pm 11.7 years, was relatively close to the mean age of a study by Akbayir et al. (34.3 \pm 13.2 years, (Akbayir et al.,2005) where 39 subjects with IBD were shown to have an increasing trend for SNHL with age. Two-thirds of patients with IBD in the present study had CD (66.7%), and the most frequent location was at the ileocolonic site (95.4%); only one-third of patients had UC. This finding is broadly consistent with the report by Akbayir et al. (2005) who described a cohort of IBD patients, of whom 53.8% had the CD subtype (Akbayir et al.,2005) and 42.8% had ileocolonic involvement. Conversely, CD comprised only 24% of the cohort in a different study. Also, almost half of the cohort in the present study reported the use of corticosteroids (42.2%). This is similar to results from one study that recorded the use of corticosteroids by patients

Table 3: Hearing evaluation (Clinical, tympanometry & pure tone audiometry) of patients with Inflammatory Bowel Disease (n=33)

Tools	N (%)
Otосcopy	
Normal	32 (97)
Abnormal	1 (3.0)
Right tympanometry type	
Type 1	30 (90.9)
Type 3	3 (9.1)
Left tympanometry type	
Type 1	28 (84.8)
Type 2	1 (3.0)
Type 3	4 (12.1)
Right pure tone audiometry	
Normal	24 (72.7)
CHL	2 (6.1)
SNHL	7 (21.2)
Left pure tone audiometry	23 (69.7)
Normal	1 (3.0)
CHL	7 (21.2)
SNHL	2 (6.1)
Mixed hearing loss	
Degrees of hearing loss	
Normal	22 (66.7)
Mild	10 (30.3)
Moderate	1 (3.0)

IBD: Inflammatory Bowel Disease, CHL: Conductive Hearing Loss, SNHL: Sensorineural hearing loss

at different time points during their illness Kalyoncu et al.,. It has been shown that corticosteroids may be administered to patients with vestibular-related dysfunction to prevent hearing loss. [15] No relationship between the location of disease or corticosteroid use and SNHL was identified in our statistical analysis (Table 1).

The present study showed normal findings on otoscopy (97%), tympanometry (right: 90.9%; left: 84.4%), and pure tone audiometry (right: 72.7%; left: 69.7%) (Table 3). This agrees with the results of a prospective study by Akbayir et al. (2005), All subjects with CD or UC and controls had normal otoscopy results and unremarkable tympanometry (excluding the middle ear and conductive hearing loss). Kalyoncu et al. (2010) also reported no abnormalities in pure tone audiometry assessment in children with IBD. In the present study, analysis using left and right, pure tone audiometry revealed SNHL in 21.1% and 21.2% of subjects, respectively (Table 3). Akbayir et al. (2005) showed the presence of detectable SNHL (bilateral) in patients with IBD using pure tone audiometry, a rate that is twice the estimate reported here (46.1%; CD =12, UC = 6). A relatively higher rate of SNHL was observed in the work of Karmody et al. (2010), in which the majority of IBD patients (57.9%) (n=38) were found to have SNHL (Table 3). SNHL is said to be immune-related and hypothetically connected with T-lymphocyte-facilitated cytotoxicity and vasculitis, which affect the inner ear (Summers,1982; Billings,2004; Ruckenstein,2004).

In a bivariate analysis, the proportion of patients with and without SNHL was found not to be significantly different with respect to various demographic, environmental, and medical factors, such as age, sex, smoking history, IBD medication, extraintestinal manifestations, hearing loss factors, and IBD subtype. This attests to the absence of potential predictors of

Table 4. Comparison of clinic-demographic and medications between patients with and without SNHL.

Variable	Patients with no SNHL (n=24) N (%) or mean \pm SD	Patients with SNHL (n=9) N (%) or mean \pm SD	P value
Age (years)	30.4 \pm 11.5	35.8 \pm 11.9	0.25
Duration of illness	6.44 \pm 5.4	6.0 \pm 2.6	0.76
Gender			0.48
Males	10 (41.7%)	5 (55.6%)	
Females	14 (58.3%)	4 (44.4%)	
Smoking			0.47
Yes	5 (25%)	1 (12.5%)	
No	15 (75%)	7 (87.5%)	
IBD type			0.09
CD	18 (75%)	4 (44.4%)	
UC	6 (25%)	5 (55.6%)	
EIMs			0.91
Yes	3 (12.5%)	1 (11.1%)	
No	21 (87.5%)	8 (88.9%)	
Family history of hearing loss			0.46
Yes	1 (4.2%)	1 (11.1%)	
No	23 (95.8%)	8 (88.9%)	
Exposure to loud noise			0.93
Yes	5 (20.8%)	2 (22.2%)	
No	19 (79.2%)	7 (77.8%)	
Physical head injury			0.91
Yes	3 (12.5%)	1 (11.1%)	
No	21 (87.5%)	8 (88.9%)	
Viral infection of inner ear			0.53
Yes	1 (4.2%)	0 (0.0%)	
No	23 (95.8%)	9 (100%)	
Disease severity CD			0.44
Remission	16 (88.9%)	3 (75%)	
Mild severity	1 (5.6%)	0 (0.0%)	
Moderate severity	1 (5.6%)	1 (25%)	
Disease severity UC			0.52
Remission	2 (33.3%)	3 (60%)	
Mild	3 (50%)	2 (40%)	
Severe	1 (16.7%)	0 (0.0%)	
Medications			
Aspirin			0.54
Yes	1 (4.2%)	0 (0.0%)	
No	23 (95.8%)	9 (100%)	
NSAID			0.91
Yes	3 (12.5%)	1 (11.1%)	
No	21 (87.5%)	8 (88.9%)	
Diuretics			0.46
Yes	1 (4.2%)	1 (11.1%)	
No	23 (95.8%)	8 (88.9%)	
Mesalamine			0.54
Yes	8 (33.3%)	2 (22.2%)	
No	16 (66.7%)	7 (77.8%)	
Corticosteroids			0.15
Yes	12 (50%)	2 (22.2%)	
No	12 (50%)	7 (77.8%)	
Azathioprine			0.30
Yes	10 (41.7%)	2 (22.2%)	
No	14 (58.3%)	7 (77.8%)	
Biological therapy			0.41
Yes	7 (29.2%)	4 (44.4%)	
No	17 (70.8%)	5 (55.6%)	

Note: Independent samples T-test done to compare between means and standard deviations, and Chi-square test to compare between frequencies. SNHL: Sensorineural hearing loss, IBD: Inflammatory Bowel Disease, EIMs: Extra-Intestinal Manifestations, CD: Crohn's disease, UC: Ulcerative colitis, NSAID: Non-steroidal anti-inflammatory drugs

SNHL in patients with IBD. This corresponds with Akbayir et al. (2005) who reported a lack of a significant correlation between SNHL and several clinical and demographic factors such as sex, age, site of involvement, disease activity, IBD medication history, and coexistence of other extra-intestinal manifestations was reported. Disease activity for CD ($r = 0.05$ and $P = 0.81$) and UC ($r = -0.13$ and $P = 0.6$) were broadly the same for these patients, regardless of whether they had hearing loss. However, one study reported a positive association between bowel disease activity and all-frequency subclinical hearing loss (Kumar et al., 2000) (Table 4).

The present study may be limited owing to its prospective design, lack of healthy control subjects, small sample size, and lack of long-term follow-up analysis. Future studies may allow for prospective long-term repeated hearing assessments in patients with IBD and comparison with findings of a matched group of healthy participants.

CONCLUSION

In assessing the ear and hearing characteristics of IBD patients, the results showed no significant relationship between IBD and SNHL. Normal findings were revealed in most patients in this cohort; the presence of SNHL was found in only a tiny proportion of patients with IBD. Thus, no clinically significant predictors of SNHL were identified.

Contributors:

Guarantor of the article: MM

Development of study concept and design: HM and MM

Acquisition, analysis, and interpretation of the data: AA, SA, IR, WA, AB, MM, OS, and HM

Statistical analysis: OS

Drafting of the manuscript: MM, MS, and OS

Critical revision of the manuscript for important intellectual content: MM, OS, HM, MS

List of Abbreviations:

IBD: Inflammatory Bowel Disease

SNHL: sensorineural hearing loss

UC: Ulcerative Colitis

CD: Crohn's Disease

KAUH: King Abdulaziz University Hospital

HBI: Harvey-Bradshaw index

IBDU: Inflammatory bowel disease undetermined

EIMs: extra-intestinal manifestations

CBC: complete blood count

CRP: C-reactive protein

dB: decibels

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