BENHA MEDICAL JOURNAL bmj

Print ISSN 1110-208X

Online ISSN 2357-0016

Original article

Outcome of Antibiotic-Impregnated Shunt (AIS) Catheters for Management of Hydrocephalus: A Retro-Prospective Study versus Non-AIS Catheters

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Received:

Accepted:

Abstract

Back ground: Ventriculoperitoneal (VP) shunt is one of the most commonly performed procedures by a neurosurgeon. It is occasionally fraught with the most bizarre complications . Shunt infection in hydrocephalus patients is the most important complication and causes a severe, even life-threatening complication. **Objectives:** To evaluate outcome of insertion of antibiotic impregnated shunt (AIS) catheter compared to non-AIS catheter for treatment hydrocephalus (HCP) in neonates. **Patients & Methods:** Prospective part of the study (Group A) included 50 patients fulfilling the diagnostic criteria for HCP and assigned to receive AIS catheter. The retrospective part included 50 n patients age- and gender-matched patients underwent non-AIS catheter for treatment of HCP. Study outcomes included rates of catheter-related infection (CRI) and revision surgery (RS) for CRI. **Results:** Sixteen patients required RS for CRI; 3 in group A and 13 in group B with significantly lower frequency in group A. Frequency of patients required early RS was significantly lower ($p<0.001$) and mean duration till development of the 1st CRI was significantly ($p=0.019$) longer in group A. Frequency of patients required frequent revision was significantly ($p=0.001$) lower in group A. Collectively, there were 25 episodes of CRI with significantly lower frequency in group A ($p=0.001$). Mean number of local CRI findings/patient was significantly ($p=0.019$) lower and duration of symptoms before diagnosis of CRI was significantly ($p=0.02$) longer in group A. Thirteen patients showed high leucocytic count, 12 patients had low CSF glucose/serum glucose and 7 patients showed high CSF lactate concentration. Bacteriological examination of replaced catheters showed significantly higher frequency of no bacterial growth in group A, the frequency

of catheters positive culture for gram-positive cocci and gram-negative bacilli were significantly lower in group A**. Conclusion:** AIS catheter allowed significant reduction of CRI and RS rates. CRI rate showed negative significant correlation with age at time of primary surgery.

Keywords: Hydrocephalus, Antibiotic impregnated shunt, catheter-related infection, Revision surgery

Introduction

Ventriculoperitoneal (VP) shunt is one of the most commonly performed procedures by a neurosurgeon. It is occasionally fraught with the most bizarre complications [(1)]. These shunt-related complications constitute a major obstacle in the management of hydrocephalus (HCP) [(2)].

Shunt-related complications varied from shunt catheter infection which accounts for about 5-15%, but it can rise up to 70% in specific high-risk subgroups [(3)] to the rare complications including intradiploic catheter migration which is an extremely rare cause of shunt malfunction [(1)] and shunt calcification which is a rare complication that occurs years later after the initial operation [(4)].

Infection remains the most significant complication of VP shunt surgery and the reported rates of cerebrospinal fluid (CSF) shunt infection vary widely across studies in patients with HCP [(5)]. Risk factors for shunt infection include surgeon's experience, duration of surgery, and intraoperative handling of the device [(6)]. Further unfavorable conditions for shunt operations are long-waiting list inducing late timing of surgery and overcrowded operating theatres. These factors can be influenced by rigorous planning and improved organization through the implementation of perioperative protocols that markedly and significantly reduced shunt infection rate in children younger than 1 year, even though no significant overall reduction in shunt infection rate was found [(7)]. In contrast, several risk factors causing shunt infection cannot be influenced including patients' age, suppressed immune system, previous infection and external CSF drainage previous to shunt implantation [(8)].

Antibiotic-impregnated shunt (AIS) catheters were designed for prevention of VP shunt infections. AIS catheters have been tested comprehensively in vitro before use in a patient, showing promising sustained antibacterial activity [(9)]. In the

literature, there are no uniform results of these kinds of shunts; decisions for using them are distinctive. Although there have been reports of the effect of these catheters on the infection rate in vivo, the published data differ in their conclusions [10, 11, 12].

The current retro-prospective study aimed to evaluate the outcome of application of antibiotic impregnated shunt (AIS) for peritoneal drainage of hydrocephalus in neonates compared to traditional non-AIS catheter.

Patients and Methods

The prospective part of the current study was conducted at Neurosurgery Departments at **governmental** Hospitals in KSA since November 2011 till March 2014 to allow a minimum follow-up period of 12-months for the last case operated upon. Hydrocephalus was suspected in neonates clinically, but diagnosis was assured on CT imaging depending on findings of **Some studies**[13,14] . Patients underwent surgery through the prospective part were grouped as group A and outcome of these patients was compared to data extracted out of files of age and sex-matched patients with HCP and were managed using the traditional non-AIS catheter (Group B).

The study protocol was approved by the Local Ethical Committee of the hospital. Parents of studied neonates signed written fully informed consent prior to inclusion in the study. The study included only patients presented with clinical manifestations of increased ICP and CT scanning showing that all patients had only HCP. Patients with manifestations of meningitis, or were immunocompromised or had history of previous surgery were excluded from the study.

Patients of group A received barium permeated shunt catheter (Bactiseal Codman, Johnson & Johnson, Boston, MA, USA) impregnated with clindamycin (0.15%) and rifampi (0.054%) which are released both into the catheter lumen and into the surrounding tissue for at least a 50-day period and cover the most common germs that arise in shunt infections

Outcome of the study

- Primary outcome measure was the rate of catheter-related infection (CRI). CRI was defined when cerebrospinal fluid (CSF) or the shunt tip was contaminated with bacteria and the patient showed clinical signs of acute bacterial meningitis and symptoms of shunt malfunction or obstruction.

Additionally, one of the following parameters of bacterial inflammation of CSF had to be positive: (i) leukocyte count of $>0.25\times10^9$/L with predominantly poly-morphonuclear cells, (ii) a CSF lactate concentration of >3.5 mmol/L and/or (iii) a glucose ratio (CSF glucose/serum glucose) of <0.4 [15, 16].

- Secondary outcome measure was the rate of revision surgery for CRI.

Statistical analysis

Obtained data were presented as mean±SD, ranges, numbers and ratios. Results were analyzed using One-way ANOVA with post-hoc Tukey HSD Test and Chi-square test (X^2 test). Statistical analysis was conducted using the SPSS (Version 15, 2006) for Windows statistical package. P value <0.05 was considered statistically significant.

Results

The study included 50 patients included in group A (the prospective part) and data of another 50 patients were included in group B (the retrospective part). Patients' enrolment data showed non-significant (p>0.05) difference between patients of both groups..

Throughout a mean duration of follow-up of 28.3±10; range: 9-48 months. Only 3 patients (6%) in group A, while 13 patients (26%) in group B developed catheter-related infection (CRI) that necessitates catheter revision surgery (RS) with significantly (p=0.006) lower frequency of CRI in group A. Only 4 patients in group B required RS for their 1st CRI within one month after primary surgery, 10 patients; 2 in group A and 8 in group B, required RS for their 1st CRI within one year after primary surgery and only 2 patients, one in each group required RS for their 1st CRI after more than one year after primary surgery with significantly lower (p<0.001) frequency of patients required early RS in group A compared to group B. Mean duration till development of the 1st CRI was significantly (p=0.019) longer in patients of group A who developed CRI compared to those of group B.

Nine patients required RS once, 5 patients required RS twice and only 2 patients in group B required RS for three times with significantly (p=0.001) lower frequency of patients required frequent RS in group A compared to group B. Collectively, 25 episodes of CRI were reported in these 16 patients for an overall frequency of CRI of 1.56 episodes/patient. Frequency of CRI

episodes in group A (one episode/patient) was significantly (p=0.001) lower compared to the frequency of episodes in group B; 1.6 episodes/patient.

All patients developed CRI presented by fever with temperature ≥38^{o}C; however, patients with CRI in group A showed significantly (p=0.035) lower temperature than those of group B. Manifestations of increased ICP was evident in all patients with non-significant (p>0.05) difference between both groups. Four patients; one in group A and 3 in group B did not show local manifestations of CRI with significant (p=0.006) difference in favor of group A. Moreover, the mean number of local findings/patient was significantly (p=0.019) lower in group A compared to group B. Duration of symptoms before diagnosis of CRI was significantly (p=0.02) longer in group A compared to group B. Out of the detected CRI episodes, 11 CT scanning; 2 scans of patients in group A and 9 scans of patients in group B showed meningeal enhancement with significant (p=0.025) difference in favor of group A.

Thirteen patients showed leucocytic count >0.25×10^{9}/L, 12 patients had glucose ratio (CSF glucose/serum glucose) of <0.4 and only 7 patients showed CSF lactate concentration >3.5 mmol/L. Mean levels of estimated parameters are shown in table 4.

Out of replaced catheters, 5 catheters gave no bacterial growth, 10 catheters gave positive culture for gram-positive cocci and 11 gave positive culture for gram-negative bacilli. The frequency of no bacterial growth was significantly higher in group A. However, the frequency of catheters gave positive culture for gram-positive cocci and gram-negative bacilli were significantly lower in group A compared to group B.

Table (1): Data of studied patients of both groups

Data				Group A (n=50)	Group B (n=50)	P value
Birth data	**GA**	**Number**	**Preterm**	22 (44%)	23 (46%)	NS
			Term	28 (56%)	27 (54%)	
		Age (weeks)	**Preterm**	30±2.3	29.4±1.8	NS
			Term	39±1.5	38.6±2	NS
	BW (gm)		**Preterm**	2210±769	2183±741	NS
			Term	3130±408	3100±404	NS
Age at time of primary surgery (weeks)			**Preterm**	7.7±5	7.6±4.7	NS
			Term	12.7±7	12.2±6.1	NS

Data are presented as numbers & mean ± SD; percentages are in parenthesis; NS: Non-significant; GA: Gestational age; BW: Body weight

Table (2): Catheter-related infection data of both groups

Data			Group A	Group B	P value
Frequency of CRI	**Yes**		3 (6%)	13 (26%)	0.006
	No		47 (94%)	37 (74%)	
Time of development of 1st CRI	**Frequency**	**<1 m**	0	4 (8%)	<0.001
		1-12 m	2 (4%)	8 (16%)	
		>12 m	1 (2%)	1 (2%)	
	Mean		10.7±3.1	4.7±3.5	0.019

Data are presented as numbers & mean ± SD; percentages are in parenthesis; CRI: catheter-related infection

Table (3): Clinical findings of patients developed catheter-related infection in both groups

Data		Group A	Group B	P value
Temperature		38.1±0.2	38.8±0.4	0.035
Manifestations of ICP	**Nausea & vomiting**	2 (66.7%)	5 (38.5%)	NS
	Poor feeding	2 (66.7%)	10 (77%)	
	Irritability	3 (100%)	11 (84.5%)	
	Reduced activity	3 (100%)	10 (77%)	
	Neck stiffness	2 (66.7%)	7 (53.8%)	
Local findings	**No**	1 (33.3%)	3 (23.1%)	0.006
	Erythema	2 (66.7%)	10 (77%)	
	Local pain	2 (66.7%)	8 (61.5%)	
	Swelling	1 (33.3%)	3 (23.1%)	
	Purulent wound discharge	0	3 (23.1%)	
	Mean finding/patient	4.7±3.5	10.7±3.1	0.019
Duration of symptoms before diagnosis of infection (days)		15±6	6.7±4.3	0.02

Data are presented as numbers & mean±SD; percentages are in parenthesis; ICP: intracranial pressure; NS: non-significant difference between both groups; $p<0.05$: significant difference between both groups

Table (4): CSF laboratory findings detected in patients developed CRI

	Frequency	Mean (±SD)
Leucocytic count (>0.25×10^9/L)	13 (81.3%)	2.25±1.4
Lactate concentration (>3.5 mmol/L)	7 (43.8%)	3.3±1.33
Glucose ratio (CSF glucose/serum glucose) of <0.4	12 (75%)	0.4±0.18

Data are presented as number; percentage are in parnthesis

Table (5): Results of bacteriological examination of catheters replaced in patients developed CRI and required RS in both groups

	Group A	Group B
No bacterial growth	1 (33.3%)	4 (19%)
Gram positive cocci	0	10 (47.7%)
Gram negative bacilli	2 (66.7%)	7 (33.3%)
Total	2 (100%)	9 (100%)

Data are presented as number; percentage are in parnthesis

Fig. 1: CT brain with bactiseal catheter. Width (Px): 1920, Height (Px): 1080 Color Depth: 24 bit (True color)

Fig.2: CT brain showes non bactiseal catheter. Width (Px): 1920, Height (Px): 1080 Color Depth: 24 bit(True color)

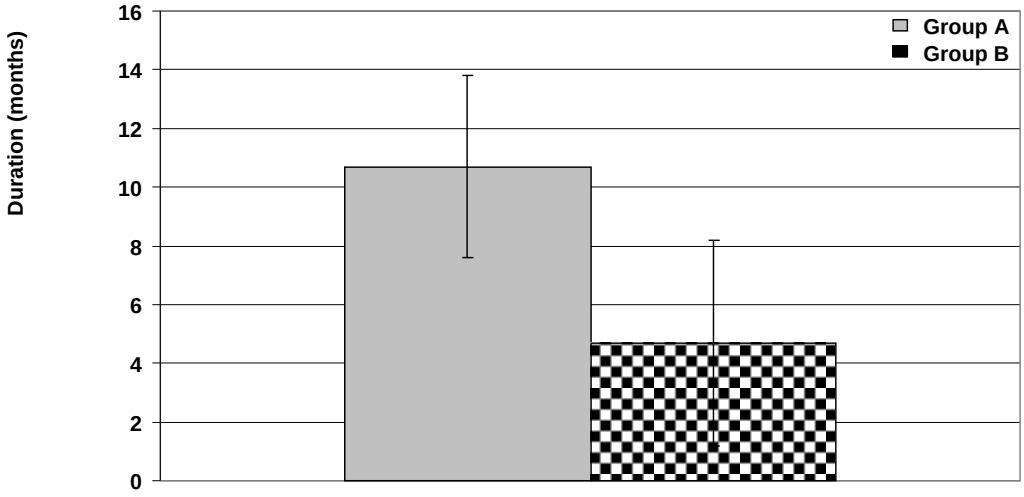

Fig. (3): Mean duration till development of 1 st catheter - related infection in patients of both groups

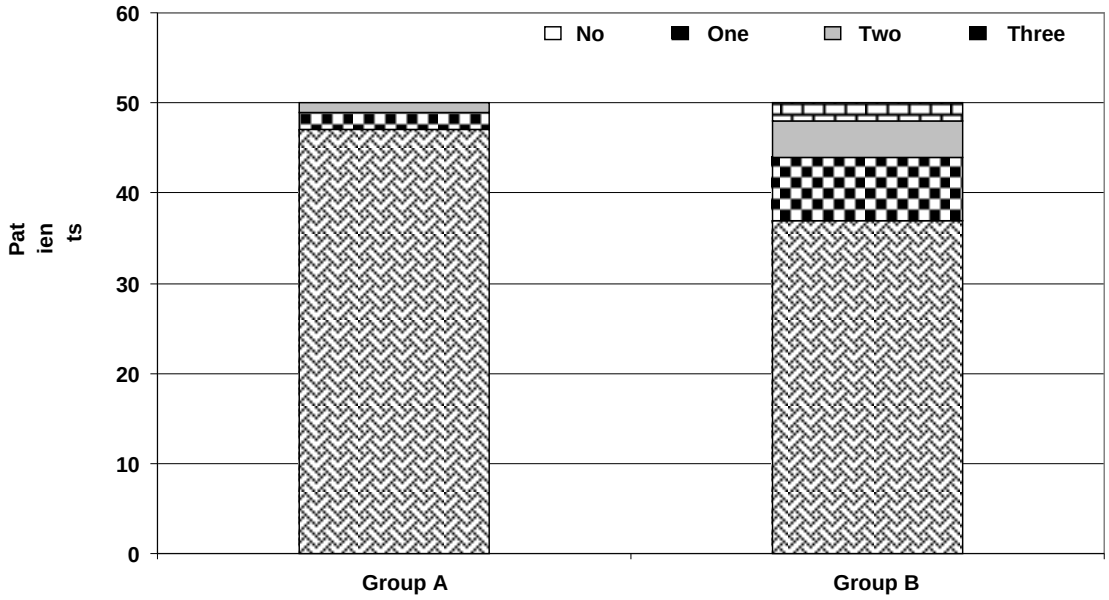

Fig . (4): Patients' distribution according to number of shunt revision trials in both groups

Discussion

The overall catheter-related infection (CRI) rate was significantly lower among patients received antibiotic-impregnated shunt (AIS) catheter (Group A) compared to patients received the standard non-AIS catheter (Group B); 6% vs. 26%; $p<0.05$. Moreover, CRI rate among both preterm (9.1%) and full-term neonates (3.6%) of group A was significantly lower compared to those of group B (30.4% and 18.5%), respectively.

The reported decreased rate of CRI with AIS coincided with Some studies **.** [17] who found the CRI frequency significantly dropped from 13.6 to 3.8% with AIS and concluded that AIS catheters are seemingly a valuable addition in HCP therapy. Also, **Other studies.** [18] retrospectively reported a CRI rate of 3.2% with AIS and 11.2% with non-AIS catheters used for CSF shunt procedures for HCP in pediatric patients with significant difference in favor of AIS and concluded that AIS catheters are effective instruments to prevent peri-operative colonization of CSF shunt components.

Recently, **Some studies.** [3] reported that overall CRI rate, irrespective of age, decreased from 34% with non-AIS to 9 % with AIS that showed to have a protective effect against CRI in all the specific high-risk subgroups analyzed. Moreover, **Other Studies .** [19, 20] found AIS were associated with significant reduction in CRI rate for

both adult (2.2% vs. 3.6%) and pediatric (2.6% vs. 7.1%) patients than non-AIS catheters regardless of hospital size, annual shunt volume, hospital location, or patient risk factors. Both studies [20, 21] documented that AIS catheters remained associated with a reduced infection rate in multivariate analysis and concluded that the use of AIS catheters may represent a reliable means of reducing CRI.

The overall frequency of CRI episodes was 1.56 episode/ patient; with significantly lower frequency in group A (one episode/patient) versus group B (1.6 episode/patient). Similarly **Some studies.** [21] documented that CRI was 1.96 times more likely to occur in patients who received non-AIS than AIS catheter. Recently, **Other studies.** [22] reported that out of a total of 87 procedures performed in 40 patients; 23 were initial placements and 64 revisions in 17 patients for a rate of 3.8/patient.

The duration till development of CRI was significantly longer and the frequency of local CRI-associated signs was significantly lower with AIS compared to non-AIS catheter. In accordance with this finding **Farber et al.** [23] reported that overall CRI occurred within a mean of 2±2 months postoperatively with significant difference in favor of AIS.

In addition to the reported significantly reduced frequency of revision surgery (RS) with AIS, the number of patients required frequent RS in group A was significantly lower than in group B. In support of this finding, **Some studies.** [24] reported that 20.2, 7.5 and 6.9% of patients required one, two, or three or more RS, respectively on using non-AIS standard catheter.

There was a negative significant correlation between age at time of primary surgery and development of CRI. Such correlation goes in hand with **Some studies.** [25] who found very prematurely born infants (gestational age < 30 weeks) were at a greater risk of CRI and **Other studies.** [26] indicated that age at shunt placement was independently and significantly associated with the shunt survival. Moreover, **Other studies.** [27] found that age younger than 6 months at first shunt placement was independently associated with reduced shunt survival. Recently, **Some studies.** [22] found younger age at stent catheter placement was associated with decreased time to proximal failure and **Other studies** [28] found prematurity and age less than one month

were significant risk factors for postoperative (PO) shunt infection.

In line with the rational for application AIS, **Some studies.** [29] found antimicrobial shunt catheters (AIS, silver-coated and hydrogel-coated catheters) were associated with lower risk for CRI than conventional catheters. **Some studies.** [30] reported that the systematic application of concentrated bacitracin powder to surgical wounds prior to closure during shunt surgery may be associated with a reduction in CRI.

Recently, **Other studies** [28] reported that in congenital HCP patients submitted to VP shunt insertion, injection of prophylactic vancomycin and gentamicin in and around the shunt hardware significantly reduced the incidence of PO shunt infection. **Some studies.** [31] found the duration of catheterization was significantly longer and catheter infections tended to occur later with AI external ventriculostomy as compared with standard catheter group.

Despite calculation of costs was not the current study target; however, the significantly reduced frequency of CRI with subsequent reduction of the costs of treatment of infection including costs of applied lines of therapy and consumption of hospital resources on one side and the significantly reduced frequency of RS with subsequent significant reduction of theater cost and costs of used catheters on the other side, could significantly compensate for the high cost of AIS that could be considered as resource-preserving therapeutic line for HCP.

In line with cost-reduction related advantage on using AIS; **Some studies.** [20] documented that out of analysis of large nationwide database, AIS catheters were found to be associated with a significant reduction in infection incidence resulting in tremendous cost savings. Also, **Other studies.** [32] concluded that the rate of decrease in infection with AIS was shown to have the greatest impact on the cost savings realized with its use.

Conclusion

The current comparative study between AIS and non-AIS catheters illustrated AIS catheter advantages manifested as significant reduction of catheter-related infection rates both in preterm and term neonates throughout a mean follow-up period of about 30 months. Catheter-related infection rate showed negative significant correlation with age at time of primary catheter insertion.

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To cite this article: Ahmed Elsayed Saleh, Islam Abou El Fetoh. Outcome of Antibiotic-Impregnated Shunt (AIS) Catheters for Management of Hydrocephalus: A Retro-Prospective Study versus Non-AIS Catheters. BMFJ XXX