

Benzathine Penicillin Prophylaxis in Children with Rheumatic Fever (RF)/ Rheumatic Heart Disease (RHD): A Study of Compliance

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Abstract

Aims and Objectives: To study the compliance of patients of Rheumatic fever (RF)/ Rheumatic heart disease (RHD) regarding secondary prophylaxis with injection benzathine penicillin. *Materials and Methods:* The study was conducted in the Pediatric Rheumatology Outpatients' Department (OPD) of a tertiary care teaching university affiliated hospital. Patients below 18 years of age diagnosed as Rheumatic fever/ Rheumatic heart disease following up in Pediatric Rheumatology OPD for at least 1 year for benzathine penicillin prophylaxis were included in the study. The patients diagnosed to have RF/ RHD were advised injection benzathine penicillin prophylaxis every 3 weeks. A proforma was devised for recording the clinical details of the patient- including demographic information, clinical details regarding RF/ RHD and rheumatic fever recurrences. The details of the benzathine penicillin prophylaxis taken by the patient were also recorded in the proforma. The reasons for non-compliance were noted and enlisted as per their frequency. *Results:* The study included 10 patients following up at the specialty clinic for rheumatic heart disease patients. We had 7 males and 3 females in the study. The average age was 9.7 yrs (6 years to 12 years). The average number of months of follow up for assessing the compliance was 20.7 months (12.6 months to 44 months). The average compliance (%) of the 10 patients was 89.60% (63.69% to 100%). Out of the 10 subjects, four had a recurrence of rheumatic fever manifesting in the form of congestive cardiac failure & carditis. Though most of the times the patients were not able to recall the reason for missing the dose, trip to one's native place was an important reason for missed doses besides forgetting the dates of the prophylaxis and doubts about need for the prophylaxis. *Conclusions:* Compliance of secondary prophylaxis with benzathine penicillin was about 90% in the present study. Frequent travel by patients to their native place was an important reason for missing the benzathine penicillin injections. **Key Words:** Benzathine penicillin, Cardiac, Compliance, Pediatric, Rheumatic fever, Rheumatic heart disease, Secondary Prophylaxis

Introduction

Rheumatic fever (RF) is the sequel of a throat infection caused by group A, beta-hemolytic streptococci and Rheumatic heart disease (RHD) is its most serious manifestation. Though the incidence of RF and RHD has been curbed in the developed countries, its incidence in developing countries like India is still high [1]. To prevent recurrences of RF and worsening of rheumatic carditis, patients are advised prophylaxis with benzathine penicillin once in 3-4 weeks. Good compliance is a must for this prophylactic measure to be effective. Since most previous Indian studies are done on occurrence of RF/ RHD, its clinical manifestations and the different ways of carrying out primary and secondary prevention, we decided to take a step further by assessing the patient's compliance to benzathine penicillin prophylaxis [1-2].

Aims and Objectives:

To study the compliance of patients of Rheumatic fever (RF)/ Rheumatic heart disease (RHD) regarding secondary prophylaxis with injection benzathine penicillin and to document the reasons for missing the doses.

Materials and Methods

The study was conducted in the Pediatric Rheumatology Outpatients' Department (OPD) of a tertiary care teaching university affiliated hospital. The clinical records of the patients are maintained with the patient and a copy of the same is preserved in the record files of the department. The patients diagnosed to have RF/ RHD are advised injection benzathine penicillin prophylaxis every 3 weeks. *Study population:* Patients below 18 years of age diagnosed as Rheumatic fever/ Rheumatic heart disease following up in Pediatric Rheumatology OPD for at least 1 year for benzathine penicillin prophylaxis were included in the study. Patients with a follow up of less than one year and those who refused to participate in the study were excluded. *Ethical Considerations:* The study was conducted after obtaining permission from the Institutional Ethics Committee. An informed consent was obtained from father/ mother/ guardian of the patient for participation in the study. Assent was also obtained from the patients. *Methods:* A proforma was devised for recording the clinical details of the patient- including demographic information, clinical details regarding RF/ RHD and rheumatic fever recurrences. The details of the benzathine penicillin prophylaxis taken by the patient were also recorded in the proforma. Special focus was on the reasons for default in taking the benzathine penicillin prophylaxis (patients are expected to take about 17 injections per year if they are on prophylaxis with 3-weekly regimen of intramuscular injection benzathine penicillin). The details in the proforma were filled by the student investigator (AG) by referring to the patient's case sheets as well as records available in the OPD. If necessary, missing information was sought from the patient's parent/ guardian. *Statistical Analysis:* The compliance with injection benzathine penicillin prophylaxis was recorded as percent out of a 100 (number of injections taken against number of injections expected to be taken). The reasons for non-compliance were noted and enlisted as per their frequency.

Results

The study included 10 patients following up at the specialty clinic for rheumatic heart disease patients at our institute. We had 7 males and 3 females in the study. The average age was 9.7 yrs (range of 6 years to 12 years). The average number of months of follow up for assessing the compliance was 20.7 months with a range of 12.6 months to 44 months. All the patients were advised to take the intramuscular injection benzathine penicillin every 3 weeks. Some of the complaints from patients regarding the prophylaxis included long distance of travel to the hospital (one case), high cost of travel (one case), and pain during the injection (2 cases). The average compliance (%) of the 10 patients was 89.60%. The actual compliance of the patients

ranged from average of 63.69% to 100%. Out of the 10 subjects, four had a recurrence of rheumatic fever manifesting in the form of congestive cardiac failure & carditis. The actual compliance of the patients is mentioned in **Table 1**. Three out of the four recurrences were due to missing just a single dose of the prophylaxis. The reasons for missing injection doses are mentioned in **Table 2**. Though most of the times the patients were not able to recall the reason for missing the dose, trip to one's native place was an important reason for missed doses. Despite counseling, one of the guardians felt that the prophylaxis was unnecessary and had difficulty in remembering the dates the prophylaxis was due. Child unwilling/un-cooperative, economic reasons, fear of painful injections, side effects, religious beliefs and inadequate counseling were not noted as the reasons for missing the doses.

Table 1: Details regarding patient compliance to Benzathine Penicillin injections

Patient No.	Sr. No.	Year	No. of Inj. Expected to be Taken	No of Inj. Actually Taken	Compliance (%)	Total Compliance (%)	Recurrence of RF/RHD
1	1	2008	9	9	100	100	No
	2	2007	17	17	100		No
	3	2006	17	17	100		No
2	1	2008	17	11	64.7	73.53	Yes (once)
	2	2007	17	14	82.35		No
3	1	2008	8	8	100	94.12	No
	2	2007	17	15	88.23		No
4	1	2008	9	8	88.89	90.17	Yes (once)
	2	2007	17	16	94.11		No
	3	2006	16	14	87.5		No
5	1	2008	9	9	100	100	No
	2	2007	17	17	100		No
	3	2006	1	1	100		No
6	1	2008	11	10	90.9	94.74	Yes (once)
	2	2007	17	17	100		No
	3	2006	15	14	93.33		No
7	1	2008	10	9	90	95	Yes (once)
	2	2007	10	10	100		No
8	1	2008	11	11	100	88.89	No
	2	2007	17	17	100		No
	3	2006	9	6	66.67		No
9	1	2008	12	11	91.66	95.83	No
	2	2007	8	8	100		No
10	1	2008	12	5	41.67	63.69	No
	2	2007	7	6	85.7		No

Table 2: Reasons for non- compliance/missed doses of Benzathine Penicillin prophylaxis

Patient No.	Sr. No.	Date of Missed dose	Reason for Missing the Dose *
1	1	9/11/2007	5 - Injection taken in native place but no documentation
	2,3,4	9/2/2007, 29/02/2007, 30/04/2006	5 - taken some oral medicine in native place
2	1,2,3	1/5/2008, 10/4/2008, 19/03/2008	5
	4,5,6	29/02/2008, 8/2/2008, 17/01/2008	10 - Believed the child did not need anymore medications
	7,8,9	8/8/2007, 18/07/2007, 16/05/2007	10 - Difficulty in remembering the correct dates
3	1	12/4/2007	5
	2	29/01/2007	10 - Does not remember
4	1	10/1/2008	2 - Father left the house after a family argument
	2,3,4	17/10/2007, 25/5/2006, 13/04/2006	10 - Does not remember
5			Did not miss a single dose
6	1,2,3	10/4/2008, 10/1/2008, 8/7/2006	10 - Does not remember
7	1	4/4/2008	10 - Difficulty in remembering the correct dates
8	1,2,3	27/07/2006, 1/9/2006, 5/10/2006	10 - Does not remember
9	1	12/7/2008	5
10	1	From 28/02/2008 to 04/09/2008	5 - Claims to have taken two injections in native place
	2	3/1/2008	10 - Does not remember
	3	18/10/2007	5

Note: *Reasons for Missing Doses were classified as- 1. Difficulty in Traveling Long Distance; 2. Family Emergency; 3. Child Unwilling/Un-cooperative; 4. Economic Reasons; 5. Travel to Native Place; 6. Fear of Painful Injections; 7. Side Effects; 8. Religious Beliefs; 9. Inadequate Counseling; 10. Any Other Reason.

Discussion

Compliance to benzathine penicillin injections is of utmost importance in secondary prevention of RF/RHD. We had a compliance of 89.6% which compares well (92%) with previous Indian studies [2]. In fact, Soudarssanane et al have also shown that primary prevention is the definite viable economic option compared to secondary prevention of RF/RHD [3]. The major impediments to overall improvement in prevention and control of RF and RHD include amongst other reasons like economic constraints (poverty, under-nutrition, overcrowding and poor housing); limited expertise of healthcare providers in prevention and management of RF and RHD; limited supplies of penicillin and limited accessibility to health centres; low levels of

awareness and involvement of the healthcare system, patients, their families and the community; poor adherence of patients to secondary prophylaxis, etc [4]. Frequent visits to native place was an important reason for missing the prophylaxis in our study. Besides forgetting that they have to take the benzathine penicillin injection while in their native place, substitution of medications by local quacks and non-documentation of the dose and drug taken also is major hindrance in ensuring good compliance. Kassem et al have shown that the RF recurrence rate and the RF attack rate were significantly higher in the group of patients on the 4-weekly schedule and demonstrated that 2-weekly benzathine penicillin schedule is superior than 4-weekly schedule in the adequate control of RF recurrences [5]. Lue et al have shown that the outcome of patients with RF is better with a 3-week than with a 4-week penicillin prophylaxis regimen [6]. This is the reason that we have been using a 3 weekly schedule to balance the number of injections received by the patients and ensuring the prevention of future attacks of RF. Walker et al showed that the defaulters to penicillin prophylaxis were more likely to be coloured, male, > 12 years old, living 10-99 km from the hospital, on several drugs and despite more frequent appointments, usually had a record of poor attendance [7]. The severity of the underlying heart disease and use of parenteral penicillin did not affect compliance [7]. They concluded that since the use of regular penicillin prophylaxis for the secondary prevention of RF is an essential step in reducing the prevalence of RHD, rheumatic fever clinics should be structured to address the needs of adolescents and the use of neighbourhood clinics for routine therapy between visits to a rheumatic fever clinic would be essential to improve the compliance [7]. Bassili et al in their study from Alexandria, showed that prophylactic failure occurred in one-third of the patients, raising doubts about the efficacy of the brands of penicillin prescribed [8]. Recurrence of rheumatic fever was recorded in 37.3% of the patients, with semirurban or rural residence and non-compliance with secondary prophylaxis were the significant risk factors [8]. The authors suggested the need for a more effective strategy of primary and secondary prophylaxis for controlling rheumatic fever in Alexandria [8]. Poor compliance with daily penicillin prophylaxis has been shown to be associated with male sex, large sibship, increased numbers of impulsive-like behaviors both at home and at school, relatively poor academic progress, low maternal educational level, previous recurrences of acute RF, etc [9]. In an interesting study by Mincham et al, compliance with medications was closely linked with positive patient-staff interactions in patients with RF/RHD [10]. From the perspective of health care, living in a remote location was frequently described as a negative influence [10]. Grayson et al have shown that a community-based nurse-led secondary prophylaxis programme for RHD is able to deliver excellent patient compliance levels [11]. Nordet et al have shown that prevention and control of RF/RHD is feasible and affordable in developing countries, by adapting WHO recommendations to the healthcare system and facilities of specific areas or provinces [4]. The training of healthcare personnel, health education for the population, and the dissemination of simple posters and educational material at least once or twice a year play an important role in the successful implementation of the programme [4]. There is a need of such outreach programs in India as well.

Conclusions: Compliance of secondary prophylaxis with benzathine penicillin was about 90% in the present study. Frequent travel by patients to their native place was an important reason for missing the penicillin injections.

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