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# An Intervention of Telemonitoring and Structured Telephone Support for Children with Bronchial Asthma: A Randomized Controlled Trial

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## Abstract

**Introduction:** Asthma is a chronic health disorder affecting a substantial proportion of children and adults worldwide. The use of technology in facilitating monitoring and follow up can be useful in better control of asthma. The aim of our study was to evaluate the effect of telemonitoring and structured telephone support as an intervention in home management of bronchial asthma in children and to study the effect of intervention on quality of life in children with bronchial asthma.

**Methods:** This study was conducted in 68 asthmatic children. Children in intervention group were doing daily PEFR at home, received home visit by e health worker related to telemedicine department and had facility to contact health professional through telephone calls.

**Results:** During study period of 6 months, the mean of rescue therapy of group-I (intervention) and group–II (control) were 4.90 and 3.22 respectively. Intervention and control group had significant difference in the number of use of rescue therapy, p value <0.0001. Although intervention group had slightly more emergency room visits mean for group-I (intervention) 1.06 and for group-II (control) 1.00 with no significant difference between them had p value of 0.540. Both the groups showed improvement in the quality of life at the end of study over period of 6 months with no significant difference, p value of 0.975(> 0.05).

**Conclusion:** The randomized controlled trial showed that telemonitoring and structured telephone support is as effective as conventional OPD based care in improving quality of life and preventing severe exacerbation leading to emergency room visit in children with moderate persistent asthma.

**Keywords:** Asthma; PEFR; Telemonitoring;

## Introduction

Asthma is a chronic disease which is most common in childhood, management of this disease is a major concern for any health organization. In asthma, the most cause of therapeutic failure is the incorrect use of drugs and drug delivery devices [1]. To prevent the failure of outpatient therapy, two steps are most effective [2]. First, improvement in patient education and second, accurate monitoring of children with asthma compared to the episodic unscheduled care and hospitalization, appropriate ambulatory care is more cost effective [3]. Frequent monitoring, follow up and education reinforcement is costly and inconvenient. The new tools in information technology handle these complex algorithms easily through a unique way of communication [4]. The involvement of information technology and its advantages can be amplified in the treatment of asthmatic subjects. The present study was conducted to evaluate a internet based intervention to facilitate the asthma control at home compared to a control group that was given standard clinic-based follow up.

## Methodology

We initiated the study after obtaining the clearance from Institute Ethics committee and subjects were enrolled with the written informed consent of parents and assent of children themselves. It was an open prospective randomized controlled trial (parallel design) in a community setting in an urban north Indian city, the union territory of Chandigarh and e-Health and telemedicine facility at a tertiary care referral hospital. The inclusion criteria were: children (6-16 yrs) with physician diagnosed persistent asthma that were asymptomatic, had PEFR between 60-80% of expected and were staying in Chandigarh.

### Sample size

Taking as binary outcome equivalence trial. In order to detect an effect size of 15% in outcomes between two treatment arms with an alpha error of 0.05 and power of 80%, and percentage success overall 95%, smallest number of subjects in each group should be 34. The total sample size required was 68.

### Methods

Children with moderate persistent asthma who had satisfied inclusion criteria were offered to get enrolled into the study. After obtaining informed consent they were randomized (computer generated randomization) into two groups. And observed for 6 months.

At the time of enrollment, the details history with particular reference to symptoms, personal history, known allergies and family history of asthma was taken. Each child underwent a thorough physical examination including anthropometric measurement, general examination and systemic examination. Children were educated regarding avoiding triggers for acute attack/daily management plan including need for adherence to therapy / action plan for asthma exacerbation. Baseline PEFR and spirometry (if possible) were recorded as per the recommendations of the American Thoracic Society.

The subjects were divided into two groups at the time of enrollment based on randomization; Group I and Group II. "Group I" received the intervention in the form of Telemonitoring in real time as well as "store and forward technique" (Telecommunication technique in which consultation is sent to the referral centre where it is kept and sent at a later time after the discussion with the specialist to the connecting centre) mode. Real-time interaction between patient and health care providers was done through a structured telephone support (landline and cell phone).

"Store and forward" mode is a telecommunation technique in which a typed consultations is sent from a connecting centre to the referral centre where it is kept, and a reply is given at a later time to the connecting centre after the query has been discussed with the specialist. This mode was used in the intervention group to address any problems arising at the patient's home-setting using a specialized special software "eSanjeevani", which is available in the telemedicine department. The parents, as well as the index child, were educated to record PEFR at home daily during morning hours and the family was provided PEFR monogram for age and height of the child for taking rescue therapy. The details were sent to and analyzed by the study Investigators, residents and consultants related to telemedicine. Clinical decisions made were communicated to children and their parents by telephone call. They were advised to take necessary corrective measures. EHealth workers involved with telemedicine had visited homes of group I patients at the interval of 2 weeks and provided education to children and their parents regarding home management, correct inhaler technique and reinforce treatment adherence.

Group 1 patients were asked to come for follow up in asthma clinic at the maximum frequency of 3 month's interval. Individuals in Group 2 had received routine follow up care in asthma clinic. Patient's profile was recorded at the enrollment, at 3 months and at 6 months. Both groups were instructed to report to emergency room in the event of worsening symptoms even using short acting beta-2 agonist inhaler.

At the end of study, data was collected and analyzed with respect to number of rescue puffs of β2 agonists and number of emergency room visits and quality of life questionnaire score. The quality of life measured by a local deployed culturally appropriate questionnaire.

### Outcome Variables

**Primary outcomes**

1. Number of exacerbations requiring rescue therapy in form of use of β2 agonist inhaler.
2. Number of emergency room visits.

**Secondary outcome**

- Improvement in quality of life.

## Results

Children with bronchial asthma attending Allergy and Asthma clinic of Advanced Pediatric Centre, Postgraduate Institute of Medical Education and Research, Chandigarh (India), fulfilling criteria for moderate persistent asthma either newly diagnosed or already on asthma therapy in the age group of 6 to 16 years and living in Chandigarh, were enrolled in the study. A total of 68 children were enrolled and randomized into group- I (n=34) and group-II (n=34). Group –I (intervention) managed with home based telemonitoring and structured telephone support and group - II (Control) managed in routine pediatrics asthma clinic of APC. There were no drop outs either at 3 months or 6 months of study.

Demographic data for sex distribution and entry characteristics of study population has been presented in table 1. Baseline vitals of study population, Family history of skin allergy and asthma in study population and Distribution of asthma related parameters in study population has been described in the table 2, table 3 and table 4 respectively. Table 5 showed the results of the study: the means of number of rescue therapy of group-I (intervention) and group-Il (control) are 4.90 and 3.22 respectively. Intervention and control group had significant difference in the usage of rescue therapy, (p value < 0.001). Although intervention group had slightly more emergency room visits, the mean for group-I (intervention) 1.06 and group-II (control) 1.00 had no significant difference with the p value of 0.540.

**Table 1:** Sex distribution and entry characteristics of study population

| Parameters | Group-I (n=34) | Group-II (n=34) | P value |
|---|---|---|---|
| Male (n, %) | (26, 76.5) | (27, 79.4) | 0.770 |
| Female (n, %) | (8, 23.5) | (7, 20.6) | |
| *Age (years) | 8.868 ± 2.453 | 9.324 ± 2.249 | 0.427 |
| *Weight (Kg) | 27.194 ± 8.460 | 34.894 ± 20.55 | 0.142 |
| *Height (cm) | 126.53 ± 14.821 | 127.05 ± 21.515 | 0.907 |
| *Age of onset (years) | 5.971 ± 2.678 | 6.529 ± 3.9427 | 0.6762 |
| *All the values are shown as Mean ± SD | | | |

**Table 2:** Baseline vitals of study population

| Parameters | Group-I (n=34) | Group-II (n=34) | P value |
|---|---|---|---|
| *RR (per min) | 20.88 ± 3.523 | 20.18 ± 3.630 | 0.419 |
| *HR (per min) | 102.30 ± 8.720 | 100.00 ± 6.892 | 0.239 |
| *SBP (mm Hg) | 100.14 ± 3.768 | 100.71 ± 3.230 | 0.545 |
| *DBP (mm Hg) | 63.07 ± 8.264 | 61.86 ± 4.318 | 0.689 |
| **Expectoration** | | | |
| Nil (n, %) | (20, 58.8) | (21, 61.8) | 0.571 |
| Mucoid (n, %) | (12, 35.3) | (9, 26.5) | |
| Mucipurrlent (n, %) | (2, 5.9) | (4, 11.8) | |
| **Skin rash** | **Group-I (n=33)** | **Group-II (n=32)** | |
| Absent (n, %) | (31, 93.9) | (31, 96.9) | 0.573 |
| Present (n, %) | (2, 6.1) | (1, 3.1) | |
| **Seasonal exacerbations of symptoms** | **Group-I (n=34)** | **Group-II (n=34)** | |
| Absent (n, %) | (1, 2.9) | (2, 5.9) | 0.555 |
| Present (n, %) | (33, 97.1) | (32, 94.1) | |

*All the values are shown as Mean ± SD
(RR=Respiratory rate, HR= Heart Rate, SBP= Systolic Blood Pressure and DBP= Diastolic Blood Pressure)

**Table 3:** Family history of skin allergy and asthma in study population

| | Group-I (n=34) | Group-II (n=34) | P value |
|---|---|---|---|
| **Skin allergy** | | | |
| Present (n, %) | (8, 23.5) | (1, 2.9) | 0.012 |
| Absent (n, %) | (26, 76.5) | (33, 97.1) | |
| **Asthma-FH** | | | |
| Present (n, %) | (15, 44.1) | (14, 41.2) | 0.806 |
| Absent (n, %) | (19, 55.9) | (20, 58.8) | |

**Table 4:** Distribution of asthma related parameters in study population before Intervention

| Parameters | Group-I (n=34) | Group-II (n=34) | P value |
|---|---|---|---|
| *No of wheezing Episode per year | 15.33 ± 7.371 | 16.73 ± 12.264 | 0.656 |
| *Duration of cough (month) | 27.50 ± 16.831 | 31.79 ± 22.05 | 0.378 |
| *Durations of wheezing(months) | 28.09 ± 17.415 | 29.73 ± 21.996 | 0.737 |
| *PEFR (%) | 72 ± 12.6 | 74 ± 12.4 | 0.391 |
| **Exp wheeze any time during follow up** | | | |
| Present (n, %) | (25, 73.5) | (19, 55.9) | 0.204 |
| Absent (n, %) | (9, 26.5) | (15, 44.1) | |

*****All the values are shown as Mean ± SD

**Table 5:** Primary outcome variables in study population

| Parameters | Group-I (n=34) | Group-II (n=34) | P value |
|---|---|---|---|
| *No. of rescue therapy | 4.90 ± 1.647 | 3.22 ± 1.385 | 0.100 |
| *No. emergency room visit | 1.06 ± 0.250 | 1.00 ± 0.00 | 0.333 |

*****All the values are shown as Mean ± SD

In this study, the quality of life tool was used to assess improvement in control of asthma symptoms in two groups. Quality of life questionnaire response score was recorded for 41 parameters at enrollment, at 3 months and at the end of 6 months. Only two records of each group: one at enrollment and the other at the end were selected for comparison.

Table 6 showed the mean of total quality of life response score of both groups, recorded at enrollment and at the end of 6 months. At enrollment, the means of total score of group-I (intervention) and group-II (control) were 132.14 and 133.97 with no significant difference, p value 0.649 (> 0.05). The means of total score at the end of the study for group-I and group-II were 159.79 and 158.64 respectively. Both the groups showed improvement in quality of life at the end of the study and had almost similar improvement with no significant difference, p value of 0.975 (> 0.05).

**Table 6:** Secondary outcome in quality of life in study population

| Parameters | Group-I (n=34) | Group-II (n=34) | P value |
|---|---|---|---|
| *Q total | 132.14 ± 13.14 | 133.97 ± 18.71 | 0.649 |
| *QE total | 159.79 ± 7.16 | 158.64 ± 3.122 | 0.397 |

*All the values are shown as Mean ± SD
Q=quality of life questionnaire response score at enrollment
QE= response score at the end of 6 months

## Discussion

Asthma forces a heavy burden on patients and the healthcare system. Telemedicine may provide an opportunity by which a patient can overcome the barrier of distance in search of specialty and quality care. This study focuses on the assessment of telemedicine especially in the monitoring and treatment of asthma. It is important to mention that all the patients enrolled in this study already receiving primary care, including asthma management. We observed significant and clinically relevant improvements in asthma control in children monitored with telemedicine compared to children whose asthma management was done by face-to-face interaction with the specialist. We undertook the present study as there are no such Indian studies available for the use of Telemonitoring in home management of children with bronchial asthma and assessment of its effect on symptom control and improvement in the quality of life.

The efficacy of education about asthma and self monitoring has been reported in some Indian studies also [5,6]. All these studies have shown better quality of life, better response to treatment and better peak expiratory flow rate (PEFR in the asthma education groups. The hospitalizations due to severe attacks of asthma, emergency visits and loss of productive days were all decreased in patient education groups. In this study also we found that there is no significant difference in emergency visit in both the groups.

We utilized cellular mobile services and internet in this study for the monitoring of children with asthma by making regular contact with patient as well as family. In the pediatric population asthma telemonitoring also been assessed in terms of improvement in asthma symptom control and in quality of life [7]. The study by Pinnock, et al. [7] determined asthma condition improved if we involve routine follow up by telephoning patients and a good alternative of face-to-face review. Finkelsein, et al. [5] demonstrated in 31 asthmatic patients, that self tested spirometry during telemonitoring was valid and comparable with those performed under the supervision of a trained medical professional. This study also emphasized on the idea of Internet-based home asthma telemonitoring also possible in a group of patients with no computer background [5]. One study of this type to evaluate home based Spirometry is underway in our Telemedicine centre.

The feasibility of a remote monitoring system that can be useful for asthmatic patients from their homes after discharge from hospital has also been tested in 84 subjects with success [7]. In recent studies it also shown that continuous monitoring in case of asthma also help in reducing asthma exacerbations, decrease the cost of asthma management and optimize drug therapy. Kokubu, et al. [8] developed a telemonitoring system to keep on eye upon the airway status of patients with poorly controlled asthma from their homes. Through this system a nurse, under the supervision physician, provides instructions to individuals via the telephone/mobile phone to help them manage exacerbation. This study concludes that the number of emergency visits decreased significantly and the daily routine activities of in the telemedicine group. Ostojic, et al. [9] established the predictability and usefulness of Global System for Mobile Communications (GSM) Mobile Telephone Short Message Service (SMS) for PEF monitoring. The results concluded that SMS is a reliable, convenient and secure means that may improve asthma control. A study conducted by ROMANO, et al. [10] have also shown the same result as we found in this study that asthma monitoring via telemedicine resulted in improvements in asthma control and quality of life similar to face-to-face encounters provided by specialists.

Successful treatment of a child with asthma should involve improvement in clinical parameters, and quality of life for the child and his family. However, the continuous monitoring is necessary because there are sufficient evidences that poor compliance and wrong technique of taking inhaled corticosteroid or medicine is the main problem in asthmatics [11,12]. Asthma is the main reason for repeated hospitalization and it badly affects on the quality of life of children, so there are always considerable

room for interventions to improve child's and family's quality of life and Telemedicine has been proved as the one milestone in improving quality of life without long travel, long queue of hospital and missing school or work to attend OPD [13].

## Conclusion

This study has shown that there is a significant scope of using telemedicine in increasing accessibility to healthcare facilities, continuous patient's education, decreasing geographical distance and improving quality of life in children with bronchial asthma. In coming near future, we can hope widespread use of this new frontier of technological facility in health care.

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