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THE EFFECT OF TRANSDERMAL TULOBUTEROL PATCH IN THE TREATMENT OF PEDIATRIC ASTHMA.

Paediatrics

Deepak Shivpuri* Director & HOD, Pediatrics, Fortis Escort Hospital Jaipur. *Corresponding author

Avesh Saini DNB Resident, Pediatrics, Fortis Escort Hospital Jaipur.

ABSTRACT

In this prospective, longitudinal, observational study 100 children between 5-18 years of age with partially controlled or uncontrolled asthma as per GINA 2016 guidelines were taken up for the study. This study was conducted at the department of Pediatrics, Fortis Escorts Hospital, Jaipur between November 2016 and June 2017. Of the 100 children 43% were partially controlled and 57% uncontrolled. The Tulobuterol transdermal patch was applied once daily at bedtime, in a dose of 1 mg for children 5 to <9 years and 2 mg for children ≥9 years of age. Controller therapy being given earlier was continued. Baseline Peak expiratory flow (PEF) was measured and repeated at 2 and 4 weeks after initiation of treatment. Baseline mean PEF was 138.35ml which increased to 175.11ml and 185.84ml after 2 and 4 weeks respectively (p value <0.001). After 4 weeks of Tulobuterol add on therapy, 85 % children had well controlled asthma as compared to baseline (p value <0.001).

KEYWORDS

Partially controlled Asthma, Uncontrolled Asthma. Tulobuterol Transdermal Patch

Pediatric Asthma is a major public health problem in both developed and developing countries. As many as 334 million people suffer from Asthma worldwide (Global Asthma Report 2014). In India, the prevalence of Asthma is 10% to 15% in 5-11 year old children and is rapidly increasing (Bronchial asthma Fact sheet N°206, WHO, 2016). The mainstay of controller therapy in pediatric Asthma is inhaled corticosteroids.

Tulobuterol transdermal patch (TTP) has been available since 1998 and DCGI India has approved its use since 24th April 2014 for children over 6 months of age (Drug Controller General of India, MOHFW, 2014). Previous studies show its effectiveness and lack of side effects when used in children (Katsunuma et al., 2013; Yoshihara, Yamada, Abe , Arisaka, 2006; Iikura et al., 1995; Le Bourgeois, de Blic, Chauvin, Scheinmann, Paupe, 1990; Tamura, Ichinose, Fukuchi, Miyamoto, 2012). In this study we report improvement in symptoms and PEF in children with partially controlled or uncontrolled Asthma with add on Tulobuterol therapy.

Methods

After approval by the Institutional Ethics Committee and with parental consent 100 children between 5 and 18 years of age with partially controlled or uncontrolled Asthma while on appropriate controller therapy were enrolled. Children with skin diseases such as atopic dermatitis, in whom the Tulobuterol patch was considered unsuitable, were excluded.

The Tulobuterol patch was applied once daily at bedtime to the chest, back or upper arm in a dose of 1 mg for children 5 to <9 years and 2 mg for children ≥9 years of age. A baseline PEF was noted before initiation of treatment and repeated at 2 and 4 weeks after initiation of treatment.

During this period parents were asked to measure PEF in the morning and at bedtime and to note these down in a diary along with any exacerbation symptoms and need for rescue therapy. A written Asthma Action Plan was given to manage exacerbations. Parents were asked to bring the diary during follow up visits. The level of asthma control was assessed according to GINA guidelines and PEF compared with baseline values. Data was collected in excel sheet and the efficacy of Tulobuterol transdermal patch statistically evaluated.

Results

At 2 and 4 weeks after addition of Tulobuterol patch to previous controller therapy there was a significant improvement in PEF values as compared to baseline. After 4 weeks of Tulobuterol therapy 85% children had well controlled asthma as compared to baseline (p value-<0.001) (Table 1).

Table 1. Comparison of PEF values before and after Tulobuterol transdermal patch

At 2 weeks	174.91	48.176	<0.001
At 4 weeks	185.72	47.808	<0.001
Peak expiratory flow (ml)	**Mean (ml)**	**SD**	**P Value**
Base line	138.35	47.365	<0.001

Discussion

Satisfactory control of Asthma is vital for optimal growth and development, school performance, participation in sports activities and avoidance of exacerbations.

Katsunuma et al. (2013) studied 33 and 31 pediatric patients with Tulobuterol patches and Theophylline respectively. PEF measured in the morning and before bedtime was significantly higher in the Tulobuterol patch group ($p < 0.001$) than in the theophylline group (Katsunuma et al., 2013).

Yoshihara S., Yamada Y., Abe T., Arisaka O., (2006) conducted a randomized, parallel-group, comparative study in pediatric patients with severe asthma who were under inhaled steroids (ICS). They concluded that the Tulobuterol patch combined with ICS played an important role in the long term management of asthma in children aged ≥6 months to the elderly (Yoshihara et al., 2006).

Iikura et al. (1995) studied the pharmacokinetics and pharmacody namics of tulobuterol patch (HN-078), in the treatment of childhood asthma. Peak expiratory flow rate values obtained after application of HN-078 significantly increased in comparison to those obtained before application (Iikura et al., 1995).

Le Bourgeois M., de Blic J., Chauvin JP., Scheinmann P., Paupe J., 1990 studied the effect of Tulobuterol or Albuterol in school going children. In this study there were 40 children aged 6 to 16 years with stable chronic asthma. 20 were randomly assigned to receive 40 micrograms/kg of Tulobuterol twice daily and 20 received 100 micrograms/kg of Albuterol three times daily for three months. Patients were assessed by spirometry after the morning dose of medication at 0, 2, 4, 8, and 12 weeks of treatment. They concluded that Tulobuterol was more effective than Albuterol in the treatment of asthma in children. (Le Bourgeois et al., 1990).

Tamura G., Ichinose M., Fukuchi Y., Miyamoto T. (2012) suggested that tulobuterol patch is excellent in terms of treatment adherence and convenience of use because it requires only once daily application (Tamura et al., 2012).

Our study, like previous studies, shows significant clinical improvement and PEF values with add on Tulobuterol transdermal patch.

There is no study on the use of Tulobuterol patch in Pediatric Asthma from India. One study was started in Feb 2011 by Sparsha Pharma International Pvt. Ltd, Hyderabad, Telangana, India, but no results are available.

Limitations of study

This study was conducted at a Tertiary care Multispecialty Superspecialty hospital. Hence the findings cannot be generalized for the entire population. The sample size was small and the study was done at a single center. Multicentric studies with larger sample size should be done for formulating clear guidelines for use of Transdermal Tulobuterol Patch in children.

Conclusion of study

The use of Tulobuterol transdermal patch in addition to regular controller therapy in children with partially controlled and uncontrolled Asthma provides significant relief in symptoms and peak expiratory flow rates.

REFERENCES

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2016. Available from: www.ginasthma.org
2. The Global Asthma Report 2014. Auckland, New Zealand: Global Asthma Network, 2014. www.globalasthmareport.org/resources/Global_Asthma_Report_2014.pdf
3. Bronchial asthma Fact sheet N°206, WHO Media centre, http:// www.who.int/mediacentre/factsheets/fs206/en/
4. Drug Controller General of India, Central Drugs Standard Control Organisation, Ministry of Health and Family Welfare, Government of India cdsco. nic.in/writereaddata/snd2014new.pdf
5. Katsunuma, T., Fujisawa, T., Mizuho, N., Akira, A., Nomura, I., Yamaoka, A.,… Kurihara, K. (2013). Effects of Transdermal Tulobuterol in Pediatric Asthma Patients on Long-Term Leukotriene Receptor Antagonist Therapy: Results of a Randomized, Open-Label, Multicenter Clinical Trial in Japanese Children Aged 4-12 Years; Allergology International, 62:37-43.
6. Yoshihara, S., Yamada, Y., Abe ,T., Arisaka, O. (2006). The use of patch formulation of tulobuterol, a long-acting β2-adrenoreceptor agonist, in the treatment of severe pediatric asthma. Ann Allergy Asthma Immunol, 96:879-80.
7. Iikura, Y., Uchiyama, H., Akimoto, K., Ebisawa, M., Sakaguchi, N., Tsubaki, T.,… Miura, K. (1995). Pharmacokineticsand pharmacodynamics of the tulobuterol patch, HN-078,in childhood asthma. Ann Allergy Asthma Immunol, 74:147-51. TRANSDERMAL TULOBUTEROL PATCH IN PEDIATRIC ASTHMA
8. Le Bourgeois, M., de Blic, J., Chauvin, JP., Scheinmann, P., Paupe, J. (1990) Treatment of asthma with tulobuterol or albuterol in school-age children. Clin Ther. Nov-Dec;12(6):513-9.
9. Tamura, G., Ichinose, M., Fukuchi, Y., Miyamoto, T. (2012). Transdermal Tulobuterol Patch, a Long-Acting β2-Agonist; Allergology International. 61:219-229.