Consensus Criteria

Consensus statement and guidelines for use of dilute atropine sulphate in myopia control

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Purpose: To develop a consensus statement for use of dilute atropine in control of myopia progression in children based on review of existing literature, opinions and suggestions of the members of the Group of Paediatric Ophthalmologist and Strabismologists, Mumbai (GPOS). **Methods:** Literature review, group discussions, questionnaire study and consensus building by supermajority voting. **Results:** About 65% of paediatric ophthalmologists in Mumbai have started prescribing atropine sulphate 0.01% as routine in their patients showing myopia progression. Majority of the respondents who have used it for >1 year in their patient population are extremely happy with the results. About 47% respondents expressed concerns regarding some yet unknown side effects of long-term use in our patient population. Majority of the respondents agree that it is safe and have rarely encountered side effects with its use. **Conclusion:** Atropine sulphate 0.01% is a safe and effective treatment for myopia control. Most trained paediatric ophthalmologists recommend its use in children with progressive simple myopia.

Key words: Atropine sulphate, atropine therapy, myopia control, myopia progression

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Atropine has been tried for myopia control in children since many decades. ATOM1[1] study generated renewed interest in its use. One of the barriers in its use was the side effect profile of atropine. ATOM 2[2] showed that even 0.01% atropine has a clinically significant effect on myopia progression without the side effects of blurred near vision and photophobia that are associated with higher concentrations. Subsequently, the 5-year results were also encouraging.[3] Now atropine sulphate 0.01% is commercially available in India and has received wide interest among ophthalmologists. The safety and efficacy data from Indian eyes is now available.[4]

The Group of Paediatric Ophthalmologists and Strabismologists (GPOS), Mumbai is a group of 38 fellowship-trained paediatric ophthalmologists practicing in and around Mumbai. This group has four meetings in a year and deliberates on issues related to paediatric eye care.

The GPOS decided to build a consensus statement and guidelines for use of atropine in myopia control to answer frequently asked questions.

Methods

Scope of consensus statement

1. Use of atropine as a therapy of choice in control of myopia progression
2. Inclusion and exclusion criteria for therapy
3. Dose and duration of therapy
4. Discontinuation of therapy.

Expert panel

The GPOS, Mumbai comprising of 38 fellowship-trained paediatric ophthalmologists in practice. Over two meetings and several presentations by members of the GPOS the literature pertaining to atropine use in myopia control was reviewed. A group discussion (GD) followed in which 26 members participated. From the issues discussed in the GD, a questionnaire consisting of 30 questions was designed. This questionnaire explored the current understanding, practice patterns and experience of the participants regarding the use of atropine for myopia control. The questionnaire was circulated among the members of the GPOS via e-mail. People were asked to refrain from answering the questionnaire if they had not yet started using atropine in their practice or had only been using it for <3 months. Eighteen members responded to the questionnaire. The response of one member was not considered, since the member had been using it for <3 months. Hence, only 17 responses were considered for the next step. The results were tabulated and analysed [Annexure 1]. The results were used to draft a consensus statement and practice guidelines for atropine use. The draft was debated in the next meeting of the GPOS and the consensus statement and

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guidelines was approved by voting. A supermajority of at least 80% participants was needed to approve a consensus. Each point debated and was put to vote. A show of hands decided if consensus was reached. Twenty members participated in the voting. A consensus was reached if at least 16 members agreed with it.

Results

Almost all respondent paediatric ophthalmologists in the city of Mumbai have started using atropine for myopia control in their patient population. All of them use 0.01% atropine as the starting dose.

Close to 65% respondents have started offering it as a myopia control therapy in almost all their patients with myopia progression. The remaining is more selective. About 65% respondents recommend its use in patients of 5–6 years and older. About 88% respondents recommend its use in patients as old as 12–14 years of age.

The cut off for progression used for starting therapy varied widely from 0.5–1D per year. Respondents also reported flexibility in threshold selection based on the circumstances of a particular patient.

There is no consensus on duration of therapy. However 50% respondents like to continue it for at least 2 years or till the time child is 16 years of age, whichever is earlier. Most of the respondents have some sort of target myopia in their mind before starting therapy.

Majority of respondents call their patients after 6–8 weeks to look for compliance and tolerance. Some call them after 12 weeks. Almost 25% see them straight after 6 months. About 60% of the respondents see their patients 6 monthly, while 40% see them quarterly for the duration of the therapy. Majority of doctors (70%) in the study use implied consent. But a significant minority (25%) believed in taking written consent from the patient. Majority of doctors reported good or excellent compliance of the patients on therapy perhaps reflecting the importance that society lays on myopia control and the close involvement of care takers. There is no consensus on classifying a patient as non-responder and cut offs vary widely from 0.5D in 6 months to 1D in a year.

Extremely fragmented responses were observed in the context of approach to patients who are non-responders. Majority (80%) feel that a cycloplegic refraction is must in every visit when child is on atropine therapy. About 75% feel that axial length should be included in work up to document progression.

Majority of the respondents have not reached a conclusion regarding efficacy of this treatment, while 25% are extremely happy. Sub-group analysis of doctors who have been using it for more than a year in majority of their patients showed that almost all of them were extremely happy with the outcomes.

Almost 50% feel that current literature is enough to make atropine the standard of care while 15% feel more data are needed. Many are yet undecided. About 70% doctors feel counselling for atropine increases chair time significantly.

In spite of the enthusiasm, 47% doctors caution that there may be some yet unknown adverse effects of atropine in the long-term use. Surprisingly, in spite of its still an off label use of atropine, majority of the doctors have little or no hesitation in advising it to their patients. More than 50% doctors limit its use in simple myopia only. About 30% feel that it may have a role in other types of myopia.

Opinion is split right down the middle when it comes to the question of using different concentrations for different rates of progression. However, 80% feel there may be a case for starting with higher concentrations and then moving on to lower concentration.

About 60% respondents feel there is no need for tapering before stopping it while 35% have the opposite view. An overwhelming majority feels that it is very well tolerated and that they have rarely encountered allergy, photophobia or reading difficulties in their patients needing discontinuation of the drug.

Consensus Statement

Based on GD, questionnaire survey of members and review of literature the GPOS, Mumbai have reached a consensus that atropine sulphate 0.01% should be offered to children showing progression of simple myopia. The group feels that it is a safe intervention and have rarely encountered any side effects during its use. Although the group cautions regarding it still being an off label use and potential, yet unknown late side effects.

Guidelines

1. Children between ages 5 to 14 years may be routinely offered treatment. There is no contraindication for offering it at ages <5 years and >14 years and the same may be done at the discretion of the treating physician.
2. Any subject who is progressing by more than 0.5D per year or more may be offered myopia control. Lower cut offs may be justified in children with strong family history of myopia progression especially with early onset. While higher cut offs may be used for children in whom myopia had a late onset. Some sort of target refraction should be kept in mind.
3. The group recommends counselling of caregivers before starting therapy.
4. The group recommends that written inform consent be taken before starting therapy till the time the treatment gets wide acceptance as a standard of care.
5. A baseline cycloplegic refraction and axial length measurements should be noted before starting therapy.
6. It is also necessary to do periodic follow ups during the course of therapy. The first follow up after starting therapy is recommended at 8–12 weeks. This is primarily to judge tolerance and look for any side effects. Further follow ups may be 6 monthly with cycloplegic refraction at every visit. There is no consensus on axial length measurement for documentation of progression.
7. In patients who are responding, i.e. not progressing while on therapy, the members of the group feel that the therapy is continued for 2 years or till the child reaches the age of 16 years, whichever is earlier before a trial of withdrawal under continued surveillance. There is no need to taper before withdrawal.

8. All members recommend use of commercially available 0.01% concentration at once daily dosage preferably at bedtime. There is no consensus on using variable doses for different rates of progression.
9. A child in whom the rate of progression of myopia is not reduced by half its initial rate of progression may be classified as a non-responder. It is prudent to continue therapy for at least 1 year before classifying it as a non-responder.
10. A child on atropine 0.01% eye drops may rarely complain of allergy, blurry vision for near, photophobia and headaches. This may require use of tinted lenses, bifocal glasses or discontinuation of therapy.
11. Atropine treatment is currently not recommended, presence of any other ocular or systemic co-morbidity or atropine allergy.
12. Atropine may be used in conjunction with other myopia control interventions like spending time outdoors and orthokeratology.
13. The group feels that currently the use be limited to simple myopia (exclude other forms of myopia like pathological myopia and index myopia).
14. Non-responders are occasionally encountered and may be shifted to higher concentrations of atropine or other forms of myopia control.

Conclusion

Atropine sulphate 0.01% is a safe and effective treatment for myopia control. Most trained paediatric ophthalmologists recommend its use in children with progressive simple myopia.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

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Annexure 1: Questionnaire and responses

Email Address	How Long have you been using Atropine for myopia control in your practice?	How often do you offer Atropine as a myopia progression control therapy in your practice?	What is the lower age limit of the patient for you to offer myopia control?	what is the upper age limit for you to offer myopia control	What cut off for myopia progression do you use to determine if therapy is needed	How long to you typically continue treatment before discontinuing.	Are you flexible with cutoffs and thresholds on case to case basis?	What concentration of Atropine do you use as initial dose?	8.After how many days following starting therapy do you ask the patient to follow up initially	How often do you follow up patients on atropine treatment ?	What kind of consent do you take before starting atropine therapy	What is your experience with compliance to the treatment?	When do you classify a patient as non responder?	What do you do for non responders?	Are you satisfied with the results of atropine use in your set of patients	Do you agree with the following statement: "current literature is enough to make Atropine as standard of care treatment for progressive myopia"	Do you agree with the following statement: "Counselling for atropine increases chair time significantly"	26.Do you feel that atropine may have some yet unknown side effect of prolonged use and may only become apparent after few years.	As of now, Atropine use in myopia control is OFF LABEL. Do you think it is a problem in suggesting it as therapy in your group of patients?	Do you suggest to use atropine in myopia other than school or simple myopia (eg pathological myopia, congenital myopia, index myopia)?	When considering Atropine, do you have a target refractive error in mind?	Do you believe different concentrations should be used in children with different rates of progression?	Do you believe in tapering frequency of atropine instillation before stopping it completely	Do you believe step down approach , i.e., starting with higher concentrations and moving to lower concentrations after myopia progression in controlled is a good idea?	How frequently do you have to discontinue atropine or move to lower concentrations because of side effects ?	How frequently do you have patients complaining of photophobia or reading difficulties when using 0.01 percent atropine?	How frequently do you encounter Atropine allergy in your patients?	How frequently did you ever had to stop atropine therapy because of any known systemic side effects of atropine?	Do you feel it is necessary to document axial length during the course of treatment and follow ups?	Do you feel cycloplegic refraction is necessary every time to document progression?
dr.siddharth@gmail.com	more than 1 year	Almost all patients excluding a few	5y	16y	0.75 D/yr	1y	Some-times	0.01	4-6 wk	6 month-ly	Implied consent	Most patients are compliant	progression more than 0.5 D in 6 months	continue as before	Extremely happy	Agree	Yes	Yes	Yes	No	Frequently	No	No	May-be	rarely	Rarely	rarely	nev-er	May-be	Yes
drshalinikaul@gmail.com	more than 1 year	Almost all patients excluding a few	5y	14y	0.5 D/6 months	till child is 16 yrs of age	Some-times	0.01	8 wk	6 month-ly	Implied consent	Most patients are compliant	progression more than 0.5 D in 6 months	Change the time of installation from night to morning	Extremely happy	Agree	Yes	May-be	No	Maybe	Frequently	May-be	Yes	No	rarely	Rarely	rarely	rare-ly	Yes	Yes
drmihirkothari@gmail.com	more than 1 year	Almost all patients excluding a few	3y	16y	0.5 D/yr	2y	Al-ways	0.01	6 months	6 month-ly	Implied consent	Patients are always compliant	Progression not reduced by atleast half in 1 year	Straight away start 1 percent atropine with progressive tinted glasses	Extremely happy	Strong-ly agree	No	May-be	Yes	Maybe	Always	No	Yes	No	some-times	Some-times	some-times	nev-er	No	No
neepathacker@yahoo.com	less than 1 year	Only some patients	6y	14y	0.5 D/6 months	dont now yet	Al-ways	0.01	4-6 wk	6 month-ly	Written informed consent	Most patients are compliant	progression more than 0.5 D in 6 months	Increase the concentration in steps	Somewhat happy	Agree	Yes	Yes	No	Maybe	Frequently	No	No	No	never	Never	never	nev-er	Yes	Yes
drshahyash@gmail.com	less than 6 month	In all patients with myopia progression	5y	14y	0.75 D/yr	2y	Some-times	0.01	12 wk	quar-terly	Implied consent	Most patients are compliant	Progression more than 1 D in 1 year	Increase the concentration in steps	not reached any conclusion yet	Neutral	May-be	May-be	May-be	No	Sometimes	May-be	No	No	rarely	Rarely	rarely	nev-er	May-be	Yes
hema_shankar2001@yahoo.com	more than 1 year	In all patients with myopia progression	5y	16y	0.5 D/6 months	till child is 16 yrs of age	Fre-quent-ly	0.01	6 months	6 month-ly	Implied consent	Most patients are compliant	progression more than 0.5 D in 6 months	continue as before	not reached any conclusion yet	Agree	Yes	May-be	No	No	Frequently	May-be	May-be	No	rarely	Rarely	rarely	rare-ly	Yes	Yes
anand78kumar@gmail.com	more than 1 year	In all patients with myopia progression	3y	14y	0.5 D/yr	1y	Fre-quent-ly	0.01	6 months	6 month-ly	Implied consent	Most patients are compliant	Progression more than 0.5 D in 1 year	Increase the concentration in steps	Somewhat happy	Dis-agree	Yes	Yes	Yes	Maybe	Frequently	No	No	No	never	Never	never	nev-er	Yes	No
doctorashini@gmail.com	less than 6 month	In all patients with myopia progression	6y	12y	0.5 D/6 months	6 months	Rarely	0.01	4-6 wk	quar-terly	Implied consent	Most patients are com-pliant	progression more than 0.5 D in 6 months	Not experienced	not reached any conclu-sion yet	Dis-agree	Yes	Yes	No	No	Always	No	No	No	never	Never	never	nev-er	Yes	Yes

Contd...

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dr.rushabh@gmail.com	less than 6 month	In all patients with myopia progression	5y	16y	0.5 D/6 months	1y	Sometimes	0.01	12 wk	6 monthly	Not taken yet	Only some patients are compliant	Progression not reduced by atleast half in 1 year	Straight away start 1 percent atropine with progressive tinted glasses	not reached any conclusion yet	Agree	Yes	No	No	Yes	Rarely	Maybe	Yes	No	rarely	Sometimes	sometimes	rarely	Yes	Yes
monicasamant@hotmail.com	not yet using	Only some patients	6y	14y	0.5 D/yr	1.5y	Rarely	0.01	8 wk	6 monthly	Written informed consent		Progression more than 1 D in 1 year	Discontinue atropine therapy and suggest alternatives		Neutral	No	Yes	Yes	No	Always	No	No	No					Yes	Yes
dr.riddhi@yahoo.co.in	less than 3 months	Only some patients	4y	14y	0.5 D/6 months	Till progression retards	Sometimes	0.01	12 wk	quarterly	Implied consent	Only some patients are compliant	Progression more than 0.5 D in 1 year	Not experienced this	not reached any conclusion yet	Neutral	Yes	Maybe	Yes	No	Frequently	No	Yes	No	rarely	Sometimes	rarely	rarely	Yes	Yes
suraj.bhagde@rediffmail.com	less than 6 month	In all patients with myopia progression	no lower limit	16y	0.5 D/yr	till child is 16 yrs of age	Sometimes	0.01	4-6 wk	quarterly	Implied consent	Most patients are compliant	Progression more than 0.5 D in 1 year	Atropine 1% weekly dose with PAL or Bifocals	Somewhat happy	Agree	Maybe	Maybe	No	Yes	Rarely	Maybe	No	Maybe	never	Never	never	never	Maybe	No
dratulseth@yahoo.com	less than 1 year	Only some patients	5y	14y	1.0D/yr	till child is 16 yrs of age	Always	0.01	6 months	6 monthly	Implied consent	Most patients are compliant	Progression more than 1 D in 1 year	continue as before	not reached any conclusion yet	Neutral	Yes	No	Maybe	No	Frequently	Maybe	No	Yes	rarely	Never	rarely	never	Yes	Yes
ashwinsainani@hotmail.com	less than 1 year	Only some patients	4y	14y	0.75 D/yr	I have not discontinued any Patient. But I counsel patients for minimum 2 years treatment.	Frequently	0.01	8 wk	quarterly	Implied consent	Most patients are compliant	I have not diagnosed any patient as a nonreaponder. But I would consider a Patient who has progression of more than 0.75 D a year in the first 2 years.	I have not had any non responders. I would offer alternative therapies and stop atropine.	not reached any conclusion yet	Agree	Yes	No	No	No	Sometimes	Maybe	No	No	never	Rarely	never	never	Yes	Yes

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dr_ashishdoshi@yahoo.com	more than 1 year	In all patients with myopia progression	3y	16y	0.75 D/yr	2y	Some-times	0.01	6 months	6 month-ly	Implied consent	Most patients are compliant	Progression more than 1 D in 1 year	Increase the concentration in steps	Extremely happy	Agree	Yes	Yes	No	Maybe	Frequently	No	No	No	never	Never	rarely	nev-er	Yes	Yes
drprashantmurhe@gmail.com	more than 1 year	Only some patients	5y		1.0 D/yr	Just started 1.5 years back con-tinuing still with the first patient	Al-ways	0.01	3 days to know assess dif-ficulty in near vision and any aller-gies	quar-terly	Written informed consent	Most patients are compliant	Almost all patients have responded as yet . Patient number is very less thuogh	Did not see non responders yet .	not reached any conclusion yet	Neutral	No	Yes	May-be	No	Always	Yes	Yes	No	never	Rarely	never	nev-er	May-be	Yes
39shah@gmail.com	less than 1 year	Almost all patients excluding a few	6y	12y	0.5 D/yr	2y	Some-times	0.01	4-6 wk	quar-terly	Written informed consent	Most patients are compliant	Progression more than 0.5 D in 1 year	Still waiting for results	not reached any conclusion yet	Dis-agree	Yes	Yes	May-be	Yes	Frequently	May-be	Yes	No		Never	never	nev-er	Yes	Yes