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Assessment OF Health-Related Quality OF Life USING A SELF-MADE OUTCOME MEASURE IN Duchenne Muscular Dystrophy Patients

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Abstract
Research Question: *Is this questionnaire covering all the components to be assessed, time saving and cost effective?*
Design: *Observational*
Participants: *56 Duchenne Muscular Dystrophy Children (aged 6-18 years)*
Outcome Measure: *Self-made outcome measure consisting general, mental, social and physical component.*
Results: *Only 1.8% of participants in this survey had higher scores for general health satisfaction, whereas the majority (51.8%) expressed moderate discontent. On the other hand, mental health outcomes were very stable, with 73.2% of children scoring between 51 and 75, indicating consistent psychological well-being. This was especially true for younger children (6–10 years old), who demonstrated more coping resilience as a result of assistance from their families and schools. Equal numbers of participants (46.4%) reported moderate to somewhat higher results for social health, however only 7.1% achieved high scores. With a 69.7% score over 51, physical health was the strongest area, indicating that continued medical care and physical therapy were crucial for preserving functional capacity.*
Conclusion: *The quality of life is moderate for kids with Duchenne Muscular Dystrophy. Physical health has the biggest beneficial contribution, while general health is most impacted. To enhance general well-being, a multidisciplinary strategy incorporating social interaction, psychological support, and physical therapy is necessary.*

INTRODUCTION

Muscular dystrophy (MD) refers to a group of genetic diseases that cause progressive weakness and degeneration of skeletal muscle. [1] The phrase "muscular dystrophy" refers to a group of genetic conditions that cause insufficient or non-existent glycoproteins in the plasma membrane of muscle cells, which results in progressive and extensive muscle illness. Numerous varieties of muscular dystrophy, a non-communicable disease, have distinct patterns of heredity, time of onset and pace of muscle deterioration. Different forms of this disease are brought on by distinct changes in particular genes.[15] Duchenne muscular dystrophy (DMD) is the most common form of MD during childhood. As a group, the muscular dystrophies prevail at rates of between 19.8 as well as 25.1 per 100,000. DMD reportedly prevails throughout the general population in 1.7 to 4.2 cases for each 100,000.[18] The incidence rate of DMD is 1:3500 live male birth.[2] Inheritance is caused by a mutation on the X chromosome, DMD primarily affects boys, although girls who carry the defective gene may show some symptoms. DMD results from an absence of the muscle protein dystrophin. Progressive weakness and muscle wasting caused by degenerating muscle fibers begins in upper leg and pelvis before spreading into the upper arms. [1] They might exhibit Gower's sign and have motor skills issues, such as trouble in running, hopping, and jumping. The child may struggle to climb stairs, get out of a lying position, or fall frequently. The characteristic feature known as pseudohypertrophy of the calf muscles is caused by atrophy of the thigh muscles and enlargement of the calves. Sometimes, pseudohypertrophy is observed in the deltoid, quadriceps, or forearm extensor muscles. As the condition progresses, the initial weakness of the neck flexor, abdominal, interscapular, and hip extensor muscles becomes more widespread.[18] Western blot analysis of muscle biopsy specimens can also be used to diagnose Duchenne's dystrophy since it can identify anomalies in the amount and molecular weight of dystrophin protein. Furthermore, the absence or insufficiency of dystrophin localizing to the sarcolemmal membrane can be demonstrated by immunocytochemically staining muscle with dystrophin antibodies. Although dystrophin analysis of

muscle biopsy specimens for carrier diagnosis is unreliable, carriers of the illness may have a mosaic pattern.[20]

Fig 1: Gower's sign seen in DMD Patient.

The goal of Physical Therapy intervention is to maintain muscle function by improving strength and flexibility of muscles. For maintain respiratory function, inspiratory muscle training with deep breathing

exercises are given to the patient. For preventing contractures stretching orthosis can be advised - ankle foot orthosis, knee foot orthosis for lower limb. Strengthening program can be given with the help of Thera bands, weight cuffs etc. Daily and regular physical therapy exercises is required to maintain health, function, quality of life (QOL) of the child with DMD. [6]

The world health organization quality of life group has stated quality of life (QOL) as– 'individuals perception of their position in life, in the context of culture and value system in which they live and in relation to their goals, expectations, standards and concerns'. And Health related quality of life (HRQOL) as "an individual's or a group's perceived physical and mental health over time". In some researches HRQOL in boys with DMD is bad that of children with disorder especially in the physical domain. [4]

The presence of this disease (DMD), causes a major effect on the patient and their parents /caregiver. This can be assessed by some outcome measures defined as "any report coming from patients about a health condition and its treatment". From some outcome measures, health related quality of life, that is the effect of disease and its treatment on the patient, as perceived by the patient themselves, which help in providing a good understanding of patient's subjectivity. To coping the disease in daily life, symptoms and rate of progression of DMD causes psychological burden for parents.[8] Some recent paper addressed to explore the importance of the health-related quality of life questionnaire in DMD patient and parent. The KIDSCREEN-52 Questionnaire used in children with neurological conditions to check their health-related quality of life. This questionnaire has 10 dimensions in which there are 52 items which include physical, psychological well-being. The validity of KIDSCREEN 52 questionnaire, the sample of 1194 adolescents, showing that the questionnaire is a reliable and valid outcome measure [8]. The SF-12 Health Survey is the majorly used self-report outcome measure of functional health. [9] This is 12 item questionnaire which include general, physical and emotional health. The validity of SF-12 questionnaire, showing that the sample of 1343, is a reliable and valid outcome measure.[10]The validity of Vignos and Brooke scale , the samples of 48 participant, showing that the questionnaire is a reliable and valid outcome measure which proposed functional scale and classification system aims to provide a robust framework for evaluating novel therapies and predicting patient outcomes in DMD, ultimately improving treatment effectiveness and prognostic accuracy [11]. The RAND 12 scale is the scale for quality of life which include the components like physical and mental health which correlated with depression, social engagement, and daily activities. This is a valid and reliable outcome measure.[12] The Peds QL cognitive function scale which detected the largest differences among groups of children with varying severities of the trauma as well as parents' assessment of change in cognition post injury. This scale has 8 dimensions in which there are 46 items. This scale has good validity and reliability.[13]

METHOD AND MATERIALS

A convenience sample of 56 patients with Duchenne Muscular Dystrophy (calculated using OpenEpi) participated in a six-month exploratory trial at SJS Hospital and a Primary Healthcare Center. Following a thorough screening process based on predetermined inclusion and exclusion criteria, patients and their guardians were informed of the study's goals, methodology, and rights before giving their informed consent. Physical, social, and emotional well-being were evaluated using a self-created, content-validated questionnaire. To ensure accuracy and consistency, the researcher documented the guardians' responses after administering the instrument. The questionnaire showed great reliability (Cronbach's alpha = 0.94), high expert agreement, and strong validity (I-CVI = 0.905), suggesting that it is reliable and consistent in measuring the ideal domain. While supervision during questionnaire completion reduced answer bias and guaranteed data quality, recruitment sites were chosen for their accessibility and sufficient representation.

Self-Made Outcome Measure:

HEALTH RELATED QUALITY OF LIFE QUESTIONNAIRE IN DUCHENNE MUSCULAR DYSTROPHY

NAME: **AGE/SEX:** **DATE:**

GENERAL HEALTH

1. How would you rate your health in general now in past 1 year?

- Much better now than 1 year ago **[4]**
- Somewhat better now than 1 year ago **[3]**
- About the same **[2]**

- Much worse than 1 year ago [1]

PHYSICAL HEALTH

2. Does your health limits you to do the morning activities like brushing, bathing?
- No, does not limit at all [4]
- Yes, but sometime [3]
- Yes, but limit a little bit [2]
- Yes, limits a lot [1]

3. Does your health limits you to do the moderate activity like playing indoor games?
- No, does not limit a lot [4]
- Yes, but sometime [3]
- Yes, but limits a little bit [2]
- Yes, limits a lot [1]

4. Does your health limit your strenuous activity like doing adventures like climbing, running, lifting object?
- No, does not limit at all [4]
- Yes, but sometime [3]
- Yes, but limits a little bit [2]
- Yes, limit a lot [1]

5. Is your child able to perform this test?

Test – Close your eyes and turn 360°
- Excellent [4]
- Very good [3]
- Good [2]
- Poor [1]

6. The level of exertion seen in your child after 30meter walk.
- No exertion [4]
- Light exertion [3]
- Hard exertion [2]
- Maximal exertion [1]

7. Can you walk up stair efficiently?
- Normal: Alternating feet, no rail. [4]
- Mild Impairment: Alternating feet, must use rail. [3]
- Moderate Impairment: Two feet to a stair, must use rail. [2]
- Severe Impairment: Cannot perform safely. [1]

8. While running fast, is your child able to make sharp turns?
- No, difficulty [4]
- A little bit of difficulty [3]
- Quite a bit of difficulty [2]
- Extreme difficulty or unable to perform activity [1]

9. Is your child able to walk without orthosis?
- Able to walk independently [4]
- Able to walk but aid is needed [3]
- Able to walk but have risk of fall [2]
- Need orthosis for walking [1]

MENTAL HEALTH

10. How good is your child is at mathematical calculation?
- Excellent [4]
- Good [3]
- Fair [2]
- Poor [1]

11. How often you feel cheerful?
- All of the time [4]

- Most of the time [3]
- Some of the time [2]
- None of the time [1]

12. How often your child is nervous or anxious while performing while performing day to day activity?

- None of the time [4]
- Some of the time [3]
- Most of the time [2]
- All of the time [1]

SOCIAL HEALTH

13. How much your health limit to participate in your school function and sport activity?

- No, does not limit at all [4]
- Yes, but sometime [3]
- Yes, limit a little bit [2]
- Yes, limit a lot [1]

14. Is your child likely to participate in family functions such as weddings, birthday's etc.

- All the time [4]
- Most of the time [3]
- Some of the time [2]
- All the time [1]

TOTAL SCORE - /56

INTERPRETATION-

Complete Dependent – 1 to 13
Partially Dependent – 14 to 27
Modified Dependent – 28 to 42
Independent – 43 to 56

Statistical Analysis

The self-made outcome measure was divided into four main domains: General Health, Mental Health, Social Health, and Physical Health, with an additional calculation of the Total Quality of Life (QOL) score. In this study, results were analysed on the basis of data obtained through a questionnaire survey using StatistiXL version 2. Descriptive statistics for all is expressed as means, Standard Deviation, medians, IQR, and test significance, such as Pearson correlation test and chi square test used to correlate the parameters in questionnaire with each other. Test of significance was observed <0.05.

RESULT

1.General Health

Distribution: Just 1.8% of individuals received a score higher than 76, while 51.8% received a score between 26 and 50.
The average score was 2.00 ± 0.739.
Interpretation: The majority of children expressed unhappiness with their overall well-being and sense of their health by rating their general health condition as bad to moderate.

2.Mental Health

Distribution: 10.7% of subjects scored ≥76, whereas the bulk (73.2%) scored between 51 and 75.
The average score was 7.89 ± 1.448.
Interpretation: Children's psychological well-being was comparatively better than those of other dimensions, suggesting that they may have coping mechanisms and resilience in spite of their physical disabilities.

3.Social Health

Distribution: 46.4% of respondents scored in the 26–50 and 51–75 timeframes, while 7.1% scored ≥76, indicating an equal distribution.
The average score was 4.82 ± 1.146.
Interpretation: Physical limitations and reliance on caregivers may have contributed to the moderate impact on social participation and interaction, which in turn reduced opportunities for peer engagement.

4.Physical Health

Distribution:28.6% scored ≥ 76, and 41.1% scored between 51 and 75.

The average score was 19.86 ± 5.703.

Interpretation: According to reports, physical health was the strongest domain. This could be because children who receive regular medical care and physiotherapy are able to keep their functional ability for longer periods of time.

5.Overall Quality of Life

QOL score overall: 34.57 ± 7.830.

Interpretation: In comparison to general and social health, participants' physical and mental functioning was superior, and their overall quality of life was moderate.

6.Correlation Analysis

There was a significant correlation between all dimensions (mental, social, physical, and general health) and overall QOL ($p < 0.05$).

Physical health and overall QOL had the strongest correlation, whereas general health had the weakest. This suggests that enhancing one aspect, especially physical functioning, has a beneficial impact on general well-being.

Descriptive Statistics:

The descriptive statistics of Quality of Life (QOL) domains among the 56 participants revealed notable variations across different health dimensions.

General Health had a mean score of 2.00 ± 0.739, which is comparatively low. This indicates that participants perceived their overall health status as poor to moderate.

Mental Health scored an average of 7.89 ± 1.448, showing that participants reported relatively better psychological well-being than general health.

Social Health recorded a mean score of 4.82± 1.146, reflecting moderate satisfaction with social relationship and support.

Physical Health demonstrated the highest mean score of 19.86 ± 5.703, indicating that most participants had better physical functioning compared to other domains.

The Total QOL score was 34.57 ± 7.830, suggesting that overall quality of life among participants was at a moderate level.

The analysis highlights that physical health was the strongest contributing factor to overall QOL, whereas general health was the weakest domain, pointing to participants. Dissatisfaction or limitation in their perceived general health status. Mental health and Social health were found were found to be in the moderate range, suggesting that while participants experienced some level of psychological well-being and social support, there is still scope for improvement.

Table 1: Combined Health Distribution Table

Interval	General Health (%)	Mental Health (%)	Social Health (%)	Physical Health (%)
≤ 25	25.0	0.0	0.0	0.0
26-50	51.8	16.1	46.4	30.4
51-75	21.4	73.2	46.4	41.1
≥ 76	1.8	10.7	7.1	28.6

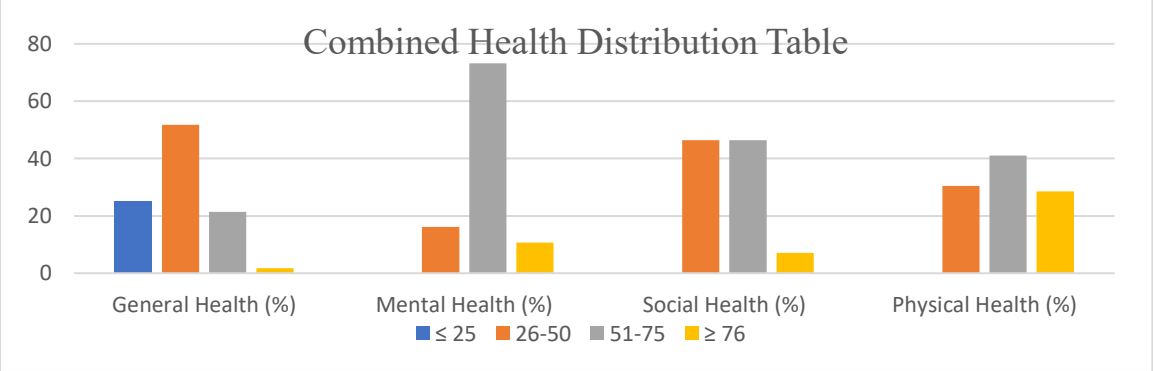

Fig 2: Combined health distribution table

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Table 2. Correlation and coefficient values:

	General Health	Mental Health	Social Health	Physical Health	Total QOL
General Health	-	2.077	2.502	3.180	4.032
Mental Health	2.077	-	4.667	5.724	8.005
Social Health	2.502	4.667	-	6.191	8.212
Physical Health	3.180	5.724	6.191	-	31.468
Total QOL	4.032	8.005	8.212	31.468	-

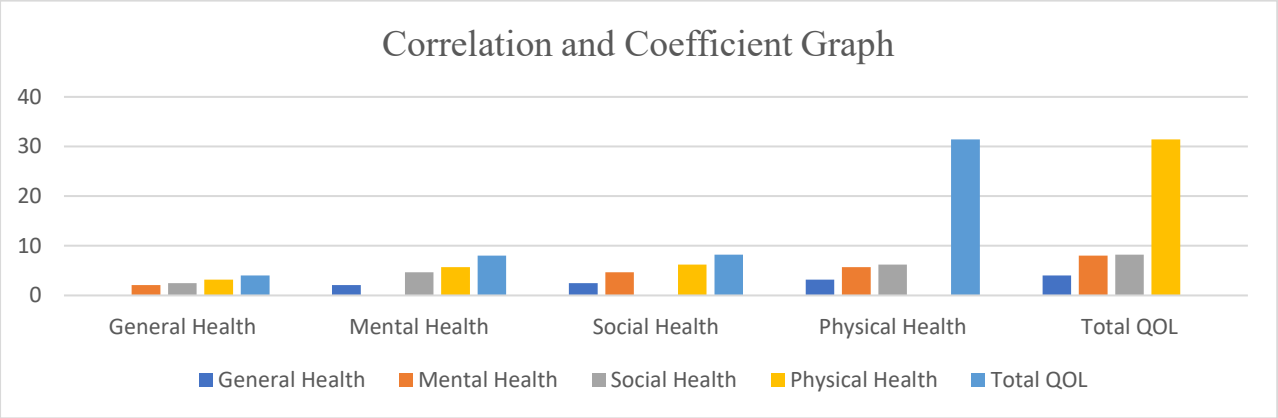

Fig 3: Correlation and coefficient graph

Table 3. Correlation Significant (p):

	General Health	Mental Health	Social Health	Physical Health	Total QOL
General Health	-	0.043	0.015	0.002	0.000
Mental Health	0.043	-	0.000	0.000	0.000
Social Health	0.015	0.000	-	0.000	0.000
Physical Health	0.002	0.000	0.000	-	0.000
Total QOL	0.000	0.000	0.000	0.000	-

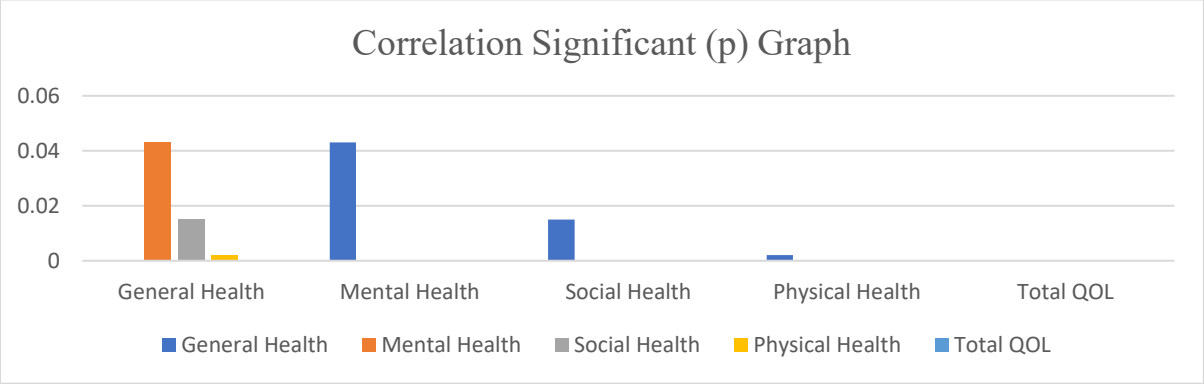

Fig 4: Correlation significant (p) graph

DISCUSSION

The severe, progressive neuromuscular disease known as Duchenne Muscular Dystrophy (DMD) impairs a child's ability to move and their psychological health. Evaluating this population's health-related quality of life (HRQoL) is essential for both directing multidisciplinary care and comprehending the patients' lived experiences. Using a self-developed outcome measure, the current study assessed HRQoL in four important domains such as general, physical, mental, and social health in boys with DMD aged 6 to 18. Overall, the results show that children with DMD have a moderate HRQoL, with the strongest category being physical health and the lowest reported assessment of general health. The questionnaire showed great reliability (Cronbach's alpha = 0.94), high expert agreement, and strong validity (I-CVI = 0.905), suggesting that it is reliable and consistent in measuring the ideal domain.

According to this research, even as physical independence diminishes, children with DMD may grow resilient and acquire coping mechanisms that support mental stability. The present study is consistent with the review by Wei, Speechley, and Campbell (2015), which showed that patients with DMD had significantly lower HRQoL than their healthy peers and kids with other chronic conditions, especially when it comes to physical functioning. The review also suggest that the severity of a disease does not always directly correlate with a decline in psychosocial HRQoL. This same pattern was also shown in the current study, as subjects maintained modest scores in the mental and social domains despite a steady decline in physical performance.

This study's key conclusion was the positive correlation found in all domains, with physical health having the largest correlation with overall HRQoL. This emphasizes how interconnected health is in DMD: physiotherapy and medical management have a direct impact on mobility and independence, but they also have a secondary positive impact on social interaction and mental health. On the other hand, accelerated physical deterioration can set off a chain reaction that results in less engagement, increased reliance, and poor self-perceptions of health. This highlights the necessity of interdisciplinary, integrated methods to care that concurrently address social, psychological, and physical factors.

The study identifies a number of consequences from a clinical point of view. Respiratory treatments, orthotic support, and physiotherapy are still essential for extending functional independence. But treatment paths should also include psychiatric counseling, especially for teenagers dealing with the emotional strain of growing dependency. Furthermore, since social isolation can worsen mental anguish and lower overall HRQoL, school-based and community-based interventions to encourage peer inclusion are essential. Since resilient and knowledgeable families are better able to support children throughout the stages of disease progression, caregiver education is equally crucial.

Despite being tailored to capture the four selected domains, the use of a self-developed HRQoL assessment restricts direct comparison with international datasets that use validated tools like the PedsQL or the DMD-specific QoL framework. Furthermore, the cross-sectional design does not record the trajectory of decline or adaptation over time; rather, it just offers a snapshot of HRQoL. Convenience sampling was used to obtain the sample, which could limit its generalizability. Future studies should use longitudinal designs to monitor changes over the course of the disease and verify culturally appropriate HRQoL metrics for DMD in India. A more thorough understanding might be possible with mixed-methods approaches that combine qualitative investigation of lived experiences with quantitative assessments.

This research concludes that HRQoL in DMD is multifaceted, with psychosocial resilience having an equally significant role as physical decline, which has the greatest impact. The results support data from around the world that contextual and social factors, in addition to medical advancement, influence HRQoL. It is clear from placing our findings in this larger body of research that enhancing HRQoL in DMD calls for social inclusion tactics, psychological support, and culturally competent care models in addition to medical interventions.

Finding of our studies was analysed on the basis of general, mental, physical and social components related to HRQoL and lead to following results:

1.In General Health- More than half of the kids (51.8% of them), were moderately unhappy with their health in general. The underlying factor that affect General health are muscle fiber breakdown, decreased stamina, frequent infections, and compromised immunity as participants age 10–18 years.

2.In Mental Health- When compared to other dimensions, the majority (73.2%) displayed rather steady psychological well-being, with scores falling between 51 and 75 interval. Younger participants (6–10 years old) frequently exhibit coping resilience because of the support they receive from their families and

schools. Stable social interaction and brain development maintain modest scores throughout adolescence, but stress, anxiety about the course of the disease, and decreased independence emerge. Although there was no significant decline in mental health in this group, neurochemical imbalances (lower levels of serotonin and dopamine) and a loss of autonomy can contribute to mental health decline with age.

3.In Social Health- Only a small percentage of participants (7.1%) had high scores for social health, with equal percentages reporting moderate (46.4%) and slightly better (46.4%) social health. Because of school and home responsibilities, younger children (6–9 years old) are more socially active. Social involvement declines with age (10–15 years), due to decreased mobility, reliance on caregivers, and challenges engaging in physical activities like sports. No participant consistently scored in the highest social range, which may be explained by the isolation, peer disengagement, and decreased community involvement that older adolescents (16–18 years old) experience as a result of the advancement of their diseases.

4. In Physical Health- With 69.7% of subjects scoring over 51, physical health was the strongest domain, suggesting that medical treatment and physiotherapy supported functionality. The 28.6% younger participants (6–9 years) maintain superior muscle strength and ambulation, which is reinforced by physiotherapy. The majority (41.1%) in the 51–75 age range are middle-aged groups (10–14 years), who start to have progressive weakness, contractures, and difficulties ascending stairs having rapid muscular deterioration, scoliosis, and decreased pulmonary capacity further impede physical functioning in older teens (15–18 years), which is why the 26–50 age group is more represented (30.4%).

Strength and Limitations:

Using a self-developed outcome measure, the study examined various facets of quality of life in children with DMD, filling a significant gap in the paediatric population in India. Reliability was increased by using both descriptive and inferential statistics, as well as a rather large sample size of 56 for an uncommon disorder. When developing comprehensive interventions, psychologists, physiotherapists, and caregivers can benefit from the findings. However, the study only included kids between the ages of 6 and 18, and the convenience sample method restricts generalizability. Despite being validated, the questionnaire was not cross-checked using common QOL tools, and because it was a cross-sectional study, it was unable to record changes over time. Furthermore, reporting bias might have been introduced by depending too much on parent-reported responses, especially in the social and mental health areas.

CONCLUSION

The general quality of life for children with Duchenne Muscular Dystrophy (DMD) was moderate. General health perception, which reflected discontent with overall well-being, was the poorest contribution, whereas physical health was the strongest. The modest impact on mental and social health indicated both social and psychological issues as well as resilience. Positive correlations were found across all dimensions, indicating that treatments that focus on one facet of QOL may have a positive impact on others. In order to maximize quality of life, the study highlights the significance of holistic, multidisciplinary management of DMD, which includes social support networks, psychological counseling, and physical therapy.

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