Research Article

Beneficial and Adverse Effects of Selective Androgen Receptor Modulators (SARMs)

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Abstract

Background: Selective androgen receptor modulators (SARMs) are a class of Performance Enhancing Drugs (PEDs) that are increasingly being abused in the fitness industry. SARMs are ligands that act differently at androgen receptors in different tissues in the body. Because of their anabolic qualities, they were initially developed for the treatment of hypogonadism, muscle wasting disorders and osteoporosis. There are currently no SARMs that have received FDA approval but still they are in use by professional athletes and recreational gym-goers which is concerning due to adverse effects like hepatotoxicity, testicular atrophy and acne.

Objective: This study aims to systematically review the existing literature and compile the beneficial and adverse effects of SARM.

Methods: The authors conducted a systematic review including articles published from 2010 to April 2023 to discover and evaluate effects of SARMs. PubMed, Google Scholar and ScienceDirect were used to search for articles using the search term: ("Selective Androgen Receptor Modulator" OR SARM OR SARMs OR "Selective Androgen Receptor Modulators") AND (Effect OR Effects). Using PRISMA guidelines 2020 (Checklist), a systematic review was performed. The authors did not perform a meta- analysis. The quality of included studies was not assessed. The Included articles reported physiologic or anatomic effects of SARMs in human subjects only. Only full-length articles written in English, published between 2010 and April 2023 were included. Articles discussing in vitro effects or discussing the synthesis, molecular properties, molecular signaling and doping control analysis of SARMs were not added. Non-original articles (reviews, letters, editorials, conference reports) were also not included.

Results: Out of 19 studies reviewed, 6 out of 19 (31.6%) discussed increase in lean body mass, 3 out of 19 (15.8%) reported increase in stairs climbing speed and 2 studies (10.52%) found out increase in leg press strength of the users. A single study (5.26%) reported a decrease in breast cancer lesion. Drug induced liver injury was the most common side effect in the users as reported by 9 out of 19 (47.3%) studies. 3 studies (15.8 %) reported hormonal imbalances and 1 study (5.26%) talked about mood swings and testicular atrophy in the users of Selective Androgen Receptor Modulators.

Conclusion: Selective Androgen Receptor Modulators are arising as a potential treatment for variety of diseases like cancer cachexia and limitation in movement due to chronic illnesses. But SARMs are related to drug induced liver injury and hormonal imbalances so their use must be discouraged by physicians. Clinical trials must be conducted to assess their uses in clinics.

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Keywords | Selective Androgen Receptor Modulators, SARMs, SARM, Beneficial effects, Adverse effects, Systematic Review.

Introduction

The abuse of Selective Androgen Receptor Modulators (SARMs) is increasing in the fitness industry. Spear-headed by inadequately educated influencers, this trend is particularly concerning.[1] The quality of information regar-

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ding SARMs provided on social media and video sharing platforms is alarmingly inadequate[2] and might lead to irresponsible use by both athletes and recreational gym-goers. Unlike testosterone, which is administered intramuscularly, SARMs can be administered enterally, making them convenient for abuse by needle-averse teenage athletes with body dysmorphia[3]. A study in the Netherlands has found that 2.7% male bodybuilders use SARMs[4]; however, the actual number is predicted to be much higher due to extreme stigma surrounding Performance Enhancing Drugs (PEDs) in the community.

A new class of tissue specific androgens has been developed to achieve desirable increase in muscle mass and physical strength without causing harmful effects like that of testosterone.[5] SARMs are ligands that act differently at androgen receptors in different tissues in the body. Traditionally used androgenic substances are steroids in nature whereas SARMs are of a diverse chemical composition with most of them being non-steroids.[6] SARMs might have many potential applications. Pharmaceutical companies have made significant efforts over the past ten years to create nonsteroidal SARMs for the treatment of muscular atrophy associated with aging, and other acute and chronic disorders.[7]

These compounds were developed in the early 2000s in order to combat harmful effects of androgen receptors agonists like testosterone (steroid in composition) primarily used by gym goers to increase body mass.[8] The major driving force behind the development of SARMs has been the ability of these substances to selectively stimulate bone and skeletal muscle growth.[9] SARMs have been investigated as potential treatments for a variety of illnesses, including Alzheimer's disease, Duchenne Muscular Dystrophy, stress incontinence, benign prostatic hyperplasia, and sarcopenia and cancer cachexia.[10] There are currently no SARMs that have received FDA approval, but still they have found their way into muscle and performance enhancement industry. Because of their anabolic qualities, these drugs are widely and illegally sold online. A survey on bodybuilding sub-reddits[11] found that 50% of SARMs users experienced side effects including mood swings, diminished testicular size, and acne. More than 90% of men stated satisfaction with their muscular gain that they believed to have derived from SARM usage. On the bleak side, greater than 50% of SARMs consumers experienced substantial adverse effects. Increased usage of these drugs is alarming because they may cause severe harmful effects like drug induced liver injury[12] and decrease in HDL- C levels.[13]

Selective Androgen Receptor Modulators have largely gone under appreciated. Individual studies have demonstrated the effects of SARMs but there is a lack of systematic reviews. This study aims to systematically review the existing literature and compile the effects of SARMs.

Methods

We conducted a systematic review of the online literature to find the most pertinent studies on the effects of SARMs. PRISMA guidelines were used in our study to conduct an exhaustive literature review. The methodologies used in this review are outlined under the following topics.

Strategy for search

A systematic review was conducted among articles published from 2010 to April 2023 to discover and evaluate the effects of SARMs. PubMed, Google Scholar and ScienceDirect were used to search for articles using the search term: ("Selective Androgen Receptor Modulator" OR SARM OR SARMs OR "Selective Androgen Receptor Modulators") AND (Effect OR Effects). The search on ScienceDirect was limited to "Titles, Abstracts, and Keywords." And the search on Google Scholar was limited to the first 20 pages.

Eligibility criteria

The Included articles reported physiologic or anatomic effects of Selective Androgen Receptor Modulators in human subjects only. Only full-text articles, published in English language between 2010 to April 2023 were included. Articles discussing in vitro effects or discussing the synthesis, molecular properties, molecular signaling and doping control analysis of SARMs were not added. Non-original articles

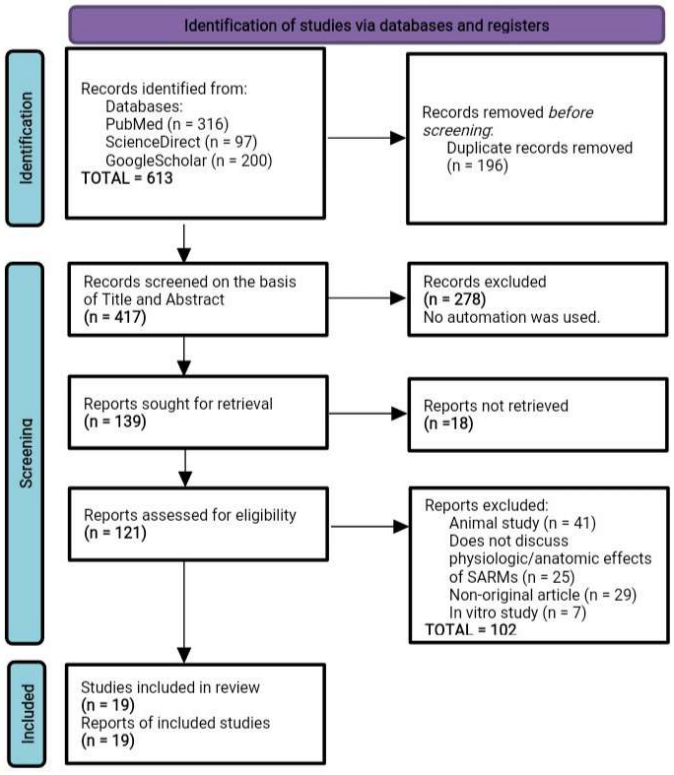

Figure 1: *PRISMA 2020 Flow Diagram*

(reviews, letters, editorials, conference reports) were also not included.

Study selection and screening:

Three authors independently filtered 417 publications on the basis of titles and abstracts during the first phase of search selection after removal of duplicates. In the next phase, 121 screened studies were read in full-text by the four authors working independently and they selected the articles on the basis of above-mentioned selection criteria. The second phase of screening was again checked by one of the 4 reviewers.

Data extraction and synthesis:

Four authors extracted and synthesized data according to PRISMA guidelines 2020. The extracted data were arranged by research characteristics, substances used, age group, and beneficial and adverse effects.

Risk of Bias Assessment:

Using PRISMA guidelines 2020 (Checklist), a systematic review was carried out. The authors did not perform a meta-analysis. The quality of included studies was not assessed.

Results

As illustrated in Figure 1, 613 papers were obtained after searching the three databases (PubMed, ScienceDirect, and Google scholar). 196 duplicates were eliminated and we screened by the titles and abstracts of the rest (n = 417), removing 278 publications. Finally, 139 articles were left. 18 articles could not be retrieved. After examining the remaining 121 arcticles on the basis of eligibility, we excluded 102 due to the reasons given in figure 1. Finally, 19 studies were included for final review.

Characteristics of the study

After systematically searching the mentioned databases and screening the search results, the authors included 19 studies in the review. Out of the 19 studies, 11 (57.9%) were Case Reports, 7 (36.9%) were Randomized Controlled Trials, and 1 (5.3%) was Cross-sectional Study.

Out of the 19 studies, 8 (42.1%) were conducted in the United States of America, 1 (5.3%) was conducted worldwide*, 1(5.3%) in Canada, 1 (5.3%) in the United Kingdom, 1(5.3%) in USA and Argentina, 1(5.3%) in England, Northern Ireland and Germany and 6 (31.6%) in undisclosed countries.

In the 19 studies discussing the effects of SARMS, the studies involved the use of the following SARMs: 5(26.3%) studies on Enobosarm, 3 (15.8%) studies on Testolone, 2 (10.5%) studies on OPK 88004, 1(5.3%) study on MK-0773, 1 (5.3%) study on Ligandrol; Testolone and Ostarine, 1 (5.3%) study on Ligandrol and S-23, 1 (5.3%) study on Ligandrol and Ibutamoren, 1 (5.3%) study on GSK-2881078, 1(5.3%) study on Spironolactone, 1(5.3%) study on Ligandrol, and 2(10.5%) studies on unknown SARMs.

Beneficial Effects Observed

A significant increase in lean body mass was reported in 6 out of 19 studies (31.6%); out of the six studies, 2 (33.3%) involved Enobosarm (also known as Ostarine), 1 (16.7%) involved MK-0773, 1(16.7%) involved OPK-88004, 1 (16.7%) involved Ligandrol; Testolone and Ostarine and 1 (16.7%) involved LGD-4033 and MK-677.

Table 1: *Characteristics of included articles (n=19)*

Sr. No	Authors	Year of Publication	Study design	Country &/or Ethnicity of Subject (s)	Intervention/ SARM usage studied	Intervention target/ Subjects	Control	Duration of SARM administration	Sample size	Age group	Beneficial Effects Observed	Adverse Effects Observed
1.	D.A. Papanicolaou et al.[14]	2013	RCT with double blind	World wide*	MK-0773 given to study group. Vitamin D and Protein supplementation in both groups	Women who are at least 65 years old and have sarcopenia	Placebo	6 months	170 (81 in the intervention and 89 in control)	65 years old and above	Significant increase in Lean Body Mass.	Increase in ALT, AST, HCT. Minor increase in systolic blood pressure.
2	Karol M. Pencina et al.[15]	2021	RCT with double blind	USA	OPK8800 4 daily in the study group	Prostate cancer survivors with no recurrence and SPPB score between 4 and 9 points.	Placebo	2 weeks	114 (57 in study and 57 in control)	19 years old and above (Average age was 67.5 years)	Significant increase in Lean Body Mass, decrease in fat mass and serum ALP.	Statistically insignificant.

3	Iakov V. Efim enkoet al.[11]	2021	Cross-sectional survey	N/A	Ligandrol (LGD4033) used by 56%, Testolone (Rad 140) used by 41.1%,Ostarine (MK 2866) used by 53.9%.	Reddit users on subreddits related to Performance Enhancing Drugs	N/A	Divide d into 3 month s and more than 3 month s	441
4	Namr atha Vontela et al.[16]	2017	Case Repor t	White- USA	Enobosarm (18 mg/d orally- 28-day cycle)	White woman with metastati c ER+, AR+, HER2- Breast Cancer	N/A	10 Cycles (i.e. 280 days)	N/A
	Harjo t Bedi et al.[17]	2021	Case Report	Canada	Ostarine (marketedas enobosarm)	Previously healthy man using Ostarine for physical development	N/	2 month s (without Medic al supervision)	N/A
6	Danie l Wein blatt and Satya jeet Roy[8]	2022	Case Report	USA	Over the counter muscle building supplement that contains Enobosarm as main ingredient (no other ingredient in the supplement	31 years old man	N/A	2 weeks	N/A
7	Wen Guo et al.[13]	2022	Phase 2 RCT with doubl e blind	USA	1of 3 doses of oral SARM (OPK- 88004) (1, 5 or 15mg daily)	Prostate cancer survivors (men)	Placebo	12 weeks	Total 114 participants (36 in the placebo arm, 28 in the 1 mg, 36 in the 5 mg, 14 in the 15 mg OPK-88004)
8	Adria n S Dobs et al.[5]	2013	RCT with double blind	American and Argentinian	Enobosarm 1mg or 3 mg	Had cancer, not obese and showed weight loss during past 6 months	Placebo	113 days	Total 159 (placebo, n=52; Enobosarm mg, n=53;Enobosarm 3 mg, n=54)
9	Mich ael Ladna et al.[12]	2023	Case report	Caucasian race	RAD140 (Testalone) powder then liquid form	young male athlete, no past medical history	none	Liquid : 2 month s, powder: unknown	NA
									25 years male
									N/A
									DILI (Jaundice, nausea, non- bloody vomiting, & severe right upper quadrant abdominal pain), raised ALT, AST and bilirubin.

3									Mood swings, testicular atrophy, acne. rare: baldness, increased blood pressure.
4							Decrease d size of some metastatic lesions. Stability in size of others.	Alopecia, facial acne, fatigue.	
								Jaundice &scleral icterus, increased liver enzymes, centrilobular cholestasis with sparse portal inflammation &mild duct damage.	
6									
7									
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9									

10	Sohai b Khan et al.[19]	Open Access Case Report	American	SARM supplements	Young male bodybuilder with no past medical history	NA	4 weeks	NA	29 years	N/A	DILI (raised LFTs, painless jaundice, pruritus, fatigue light colored stools, dark urine, intrahepatic biliary dilation, centrilobular bile stasis with lipofuscin, raised BP).		
11	Jame s T. Dalto n et al.[20]	2011	RCT With double blind	UK, Northem Ireland and Germany	Enobosarm 0.1 mg,0.3mg. 1mg,3mg	Generally healthy recruits.	Place bo	86 days	total ;120, divided in 5 groups of 24 each. (1 placebo group. Other 4 groups receiving Enobosarm doses of 0.1mg, 0.3mg, 1mg and 3mg	men above 60, post-menopausal female	Increase in lean body mass and increased stair climbing speed, decreased fat mass & insulin resistance, decreased cholesterol and TAGs, decreased FSH and LH (no effect on other sex hormones) in women, increased Hb and Hematocrit in 3mg group.	Decrease d HDL, testosterone & SHBG, headache, back pain.	
12	Brian Mala $_{ve}$[21]	2023	case report	N/A	LGD-4033 and S-23	27 Years old male weightlifter	N/A	8 weeks	N/A	27 years	N/A	Increased levels of AST, ALT, LDL, cholesterol. Decrease d HDL, LH, FSH & Testosterone.	
13	Thom as D. Carda $_{ci}$[22]	2022	case report	N/A	LGD-4033 and MK-677	A resistance exercise- trained male of 25.3 years of age	N/A	5 weeks	N/A	25 Years	Increased body mass, appendicular mass, lean body mass, increased total bone mineral and bone density and bone mineral concentration. Decrease d LDL and triglyceride levels.	Increased intramuscular testosterone and DHT levels. Decrease d total bilirubin. Post- cycle harmful effects: Decrease in HDL, body mass, total lean body mass, and total body water, BMC, BMD, ALT,AST, free testosterone and SHBG.	
14	Kenn eth Leung et al.[23]	2022	case report	N/A	RAD-140	24 Years Old Male	N/A	5 weeks	N/A	24 Years	N/A	Jaundice, Increased total bilirubin, ALP, ALT, AST, ferritin, INR, hepatomegaly, focal fatty infiltration.	

15	Divya Mohan[24]	2022	Randomized placebo control trial	N/A	GSK2881078 and Exercise (1mg orally for females and 2 mg orally for males)	47 post- menopausal women and 49 males having COPD	Placebo	13 Weeks	N/A	Placebo: average age for men and women was 64 & 64.7 years respectively. Treatment: average age for men and women	Increased leg strength in males but not in females.	Increased AST, ALT, LDL, cholesterol. Decreased LH, FSH and Testosterone, HDL.
16	Byung K. Lee et al.[25]	2022	Case report	USA	SARMS in form of health supplements	Young male	N/A	3 months	N/A	23 years old	N/A	Jaundice & DILI.
17	Wael T. Mohamed et al[26]	2023	Case report	USA	RAD-140	Young male	N/A	4 months	N/A	22 years old	N/A	Drug induced liver injury (DILI).
18	Santhanam Sundaram Peter D. Dickinson[27]	2012	Case report	UK	Spironolactone	Old male with prostate cancer	N/A	1 week	N/A	80 years old	N/A	Prostate cancer progression & bone pain.
19	ShehzadBasaria et al.[28]	2013	Double blind, placebo-controlled RCT	Boston	LGD- 4033 0.1mg, 0.3mg and 1.0mg	Non- smoking healthy men	Placebo	21 days	389	21-50 years	Increase in muscle strength, Stairs climbing speed increased, HDL levels decreased	Headache, pain and dry mouth.

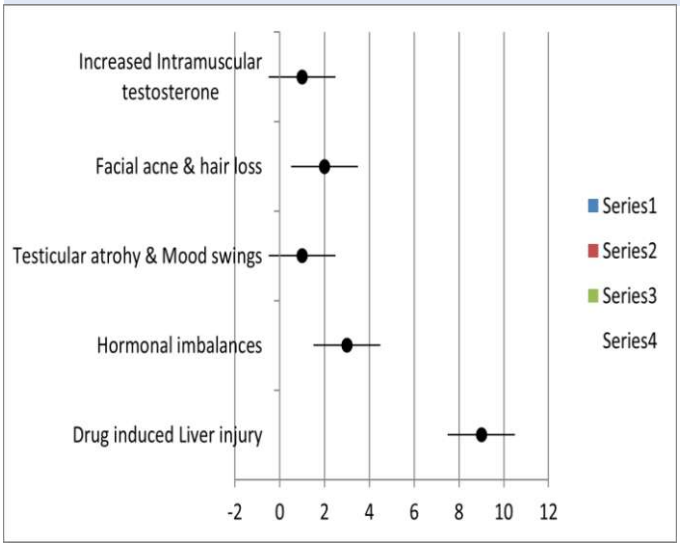

Figure 3: *Forest plot of reported studies indicating adverse effects*

Discussion

SARMs have shown significant effects in increasing muscle mass, strength and speed in both recreational users and individuals with muscle wasting diseases.

These effects show a promising clinical profile of Selective Androgen Receptor Modulators; however, Yoshimura et al. found no clear advantage in the use of SARMs in patients with sarcopenia.[29] It is to be noted that their review included only a single RCT regarding effects of SARMs on individuals with sarcopenia. Additionally, according to Christiansen et al., SARMs have a significant advantage over other forms of androgen therapy thanks to their oral bioavailability. Transdermal delivery may avoid hepatic metabolism and neutralize HDL declines, one of the only substantial negative effects of SARMs that have been reported so far.[10]

Our literature review on the beneficial and adverse effects of

selective androgen receptor modulators revealed several key findings. The reported adverse effects of SARMs in clinical trials include raised AST and ALT, disturbed blood lipid profiles, and hormonal imbalances. A cross-sectional survey of 441 individuals reported the three most common adverse reactions to SARMs, which include mood swings (22.4%), smaller testicles (20.7%), and acne (15.2%). Additional, less often mentioned side effects reported include hair loss, tiredness, irritation, yellow eyesight, and elevated blood pressure.[11]

Case reports of drug induced liver injury in recreational users were quite prevalent. These results are backed by the systematic review by Vignali et al[8]. Especially concerning are the case reports of drug induced liver injury even though this effect was not found in clinical trials; this discrepancy may be explained by the fact that recreational users often administer much higher doses of drugs.

The authors identified following limitations to our systematic review on the beneficial and adverse effects of selective androgen receptor modulators. Firstly, the availability of published literature on SARMs is still relatively limited. Furthermore, there is a lack of standardized protocols for studying and reporting the effects of SARMs, leading to heterogeneity in study designs and outcomes. Another limitation is not assessing the quality of included articles, which may have varied in terms of methodology and bias.

The effects of SARMs on individuals with wasting diseases in clinical trials show promise; SARMs confer an increase in muscle mass while avoiding the detrimental effects of traditional androgens. However, considering the conflicting findings found in some studies and a lack of long-term data, more research is needed before any clinical recommendation can be made. Also, clinical trials comparing the effects of traditional androgens and SARMs could shed more light on the practicality of SARM usage. On the other hand, it is clear that the potential harms of SARMs in re-creational users outweigh the benefits. Therefore, recreational use of SARMs should be strongly discouraged.

Conclusion

SARMS are a promising new class of anabolic agents for a myriad of indications, such as cachexia due to aging, chronic illnesses and cancer. Although the clinical-trial data look promising, more trials of SARMs are needed. Use of SARMs has also been linked to liver injury, distributed blood lipid profile and hormonal imbalance. Therefore, SARM supplementation should be strongly discouraged by healthcare professionals and patients should be advised of the potential hazards. Future research is a foremost task demonstrating further efficacy in clinically approved human trials.

Authors' Contribution:

MH: concept, MS, MH, MS, MH, MA: literature review, literature search and data extraction, MS, MH, MS, MH, **MA:** manuscript writing and final approval.

Conflict of Interest: None

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