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Adverse events in India's Ayush interventions for cervical and lumbar spondylosis: a systematic review

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Abstract

Introduction Low back and neck pain are common musculoskeletal disorders with multiple treatment options. India's traditional medical systems, known as Ayush (Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa-Rigpa and Homoeopathy) offer range of interventions and are widely used. In view of limited documentation of adverse events following Ayush interventions for lumbar and cervical spondylosis, we synthesized evidence and estimated proportion of studies reporting adverse events.

Methods We systematically searched all published documents from biomedical and multidisciplinary abstract and citation databases and Ayush-specific repositories from their inception to April 2021. We selected studies as per inclusion criteria and extracted information, adhering to PRISMA guidelines. We systematically reviewed the qualitative evidence form the selected studies.

Results Majority (94%) of the selected 113 studies were interventional studies and included 77 (68.1%) journal articles and 35 (31%) academic dissertations. Among the Ayush systems, considerable proportion was from Ayurveda (32.7%), followed by Siddha (24.8%), Yoga (22.1%), Unani (15.9%) and Homoeopathy (4.4%). Almost three-fourths of the studies were on lumbar spondylosis (65%; $n=74$), followed by cervical spondylosis (31%; $n=35$), and the remaining four included both. Thirteen percent of the 113 studies described adverse events [Yoga = 9.7%; Unani = 1.8% and Homoeopathy = 1.8%]. More adverse events were reported among the studies on lumbar (9.7%) than cervical spondylosis (2.7%). The nature of interventions were non-pharmacological (10.6%; $n=12$), pharmacological ($n=2$; 1.8%) or combined ($n=1$; 0.9%).

Conclusions Only one in eight studies reported any adverse event following Ayush interventions for cervical and lumbar spondylosis. There could be certain degree of underreporting of adverse events and requires further exploration.

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Keywords Adverse reactions, Adverse events, Ayurveda, Yoga and Naturopathy, Unani, Siddha, Homoeopathy, Musculoskeletal disorders

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Introduction

In India, other than the conventional system or biomedicine, traditional medicines are widely used [1]. These are defined as "Traditional and Non-conventional systems of health care and healing, which include Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa-Rigpa and Homoeopathy (referred by the term: Ayush), etc." As reported by India's Ministry of Health and Family Welfare, of the registered doctors, 1.2 million are from the conventional system, and 0.78 million are from the Ayush systems [1]. The utilization of Ayush system is higher among patients with chronic diseases such as skin-related and musculoskeletal ailments [2]. Low back and neck pain are prominent among all musculoskeletal disorders as per the disability burden of India. At the national level, the mean percentage change increase in Disability Adjusted Life Years from 1990 to 2016 for low back and neck pain is 66% [3]. Low back and neck pain has moved from 18th to ninth position in the leading causes of death and disability from 1990 to 2016 [3]. These two conditions are common, and many treatment options are available other than the conventional system, including Ayush, [4, 5]. The use of Ayush treatment modalities for neck and back pain is common due to its easy availability and accessibility [6].

Ayush formulations largely use plants as raw materials. Apart from the plants, resources from metals, minerals, marine and animal origin are also used for the preparation of Ayush system formulations. However, the quality issues and safety concerns of Ayurveda, Siddha, Unani, and Homoeopathy drugs have been raised from various sources [1, 7, 8]. The Ayush medications are considered to be natural molecules and are claimed to produce effects without any adverse events (AE) [9]. In addition to such pharmacological interventions, Ayush systems provide non-pharmacological interventions as an add-on or standalone modality. However, it is indispensable to document adverse events and adverse drug events (ADE) of the Ayush system's pharmacological and non-pharmacological interventions.

ADE is defined as "Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but that does not necessarily have a causal relationship with this treatment" [10]. On the other hand, AE is defined as a "Medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related" [11]. AE is a relatively broader term covering the problems from both pharmacological and non-pharmacological interventions. Detection, documentation, and reporting of AE and ADE are fundamental to pharmacovigilance activities. It is the science of assessing and monitoring the risk/benefit profiles of medications [12, 13]. In the published literature, systematic reviews of such events are available for surgical procedures, drug interventional, and manipulative therapy in the conventional systems of medicine for lumbar and cervical spondylosis [14]. However, there is no systematic review on AE of Ayush interventions for spondylosis. In this context, we aimed to synthesize evidence from the AE attributable to Ayush-based pharmacological and non-pharmacological interventions for lumbar and cervical spondylosis and compare AEs within the Ayush systems of medicine and among those two conditions.

Methods

Screening and study selection

We conducted this systematic review in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. The protocol was registered with the international prospective register of systematic reviews (PROSPERO ID: CRD42020167433) [15] and is published elsewhere [16].

We identified the key terms based on the population, intervention, outcome and Ayush-specific terms for cervical and lumbar spondylosis (Supp Table 4). We systematically searched using key terms in PubMed, Embase and Scopus. We searched Ayush-specific platforms such as Ayush research portal, Digital Helpline for Ayurveda Research Articles (DHARA), and Shodhganga, a postgraduate thesis repository. We also checked for the reports and published documents of India's National Pharmacovigilance Co-ordination Centres (NPvCC), Intermediary Pharmacovigilance Co-ordination Centres (IPvCCs) and Peripheral Pharmacovigilance Co-ordination Centres (PPvCC) of Ayush. Search terms used for different databases and the number of results are given in Supplementary Table 5. We included the articles only in English language and published upto April 2021. According to the inclusion criteria (Supp Table 3), search results were screened for eligibility based on the PICOS strategy. Population (cervical or lumbar spondylosis), Interventions (Ayush-Ayurveda/Yoga and Naturopathy/Unani/Siddha/Homoeopathy), no comparator was considered, outcome (AE), Study design (all types of study designs). We have not considered the different duration of treatments required under each Ayush system of medicines in the present review. Selected studies from the biomedical databases multidisciplinary abstract and citation databases (Pubmed, Embase, Scopus and Google Scholar) were compiled in Zotero reference management software [17] and imported into the Rayyan web application [18] for the title and abstract screening.

Inclusion criteria:

- Cervical and lumbar spondylosis patients of any age, irrespective of gender and geographical region.

- Ayush interventions (Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa-Rigpa, and Homoeopathy) including both pharmacological and non-pharmacological interventions.
- Any type of adverse events (AE) attributable to Ayush medications and procedures.
- Randomized and non-randomized controlled trials, open clinical trials, case–control studies, cross-sectional studies, quasi-experimental studies, prospective and retrospective cohort studies, case series, and case studies, qualitative studies, dissertation and thesis.

Exclusion criteria:

- Musculoskeletal disorders other than cervical and lumbar spondylosis.
- Other than the Ayush system of medicine such as Chinese, conventional, massage, physiotherapy, etc.
- Ayush studies those don't have AE information.
- Systematic review and meta-analysis, animal studies, books, protocols, and studies with incomplete information.

Studies from other Ayush-specific repositories and websites were compiled in Microsoft Excel® before uploading to Rayyan. The authors (ER, JS) reviewed independently and screened all the titles and abstracts for their eligibility to include for the full-text review. Two independent reviewers reviewed the full text of selected articles (ER, JS). During the full-text screening, the reasons for exclusion were recorded and reported (Fig. 1).

Data extraction and management

We used a data extraction form in Microsoft Excel 2016® to collect the necessary information as per the objectives. The form included characteristics on participant (cervical, lumbar spondylosis, age, gender, etc.), study (study design, presence of comparison group, etc.), interventions (type of Ayush system, type of intervention—pharmacological/non-pharmacological, duration of treatment, dose, route of administration, etc.) and outcomes (adverse events, adverse effect, serious adverse events, adverse drug reactions, side effects, etc.). We also recorded the year of publication, publication type, author details, status of the registration of the clinical trials, obtaining informed consent from the participants, and type of blinding for randomized controlled trials. One of the reviewers (JS) extracted the reported AE, and the second reviewer (ER) cross-verified the records. Any disagreement between the reviewers is resolved with the involvement of the third reviewer (BSB) through discussion. The information was then utilized for analysis.

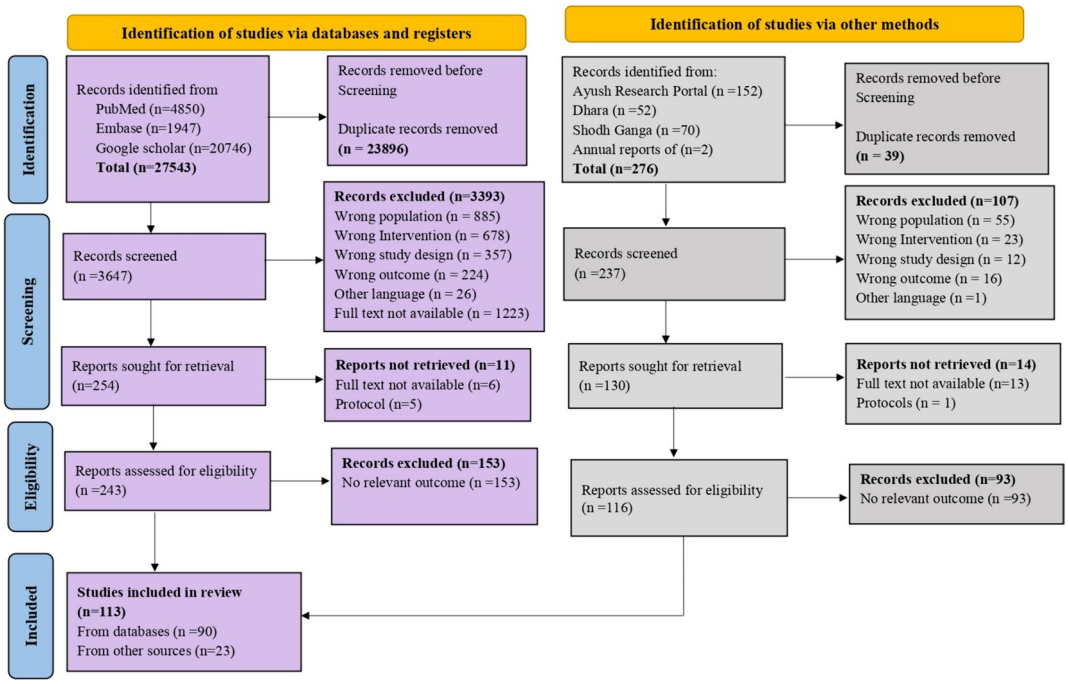

Fig. 1 Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow chart of selection of studies

Risk-of-bias assessment

The risk of bias in the selected articles was assessed using a revised Cochrane risk of bias tool (RoB-2 tool) for randomized trials, ROBINS-I tool for non-randomized studies and JBI's (formerly known as Joanna Briggs Institute) critical appraisal tool for case studies and case series. Judgement on the risk of bias was determined by the signalling questions with responses as 'yes', 'probably yes', 'probably no', 'no' and 'no information'. Two reviewers independently assessed the risk of bias; a consensus was reached through discussion for any disagreement. However, a third reviewer's opinion was obtained wherever necessary. The overall risk of bias was ascertained as high, some concerns or low for RCT; serious, moderate, low for non-RCT; low, moderate or high risk for case study and case series.

Data synthesis

A qualitative synthesis of the included articles was done based on the population, intervention and outcome. The proportion of AE was summarized based on the study condition (cervical, lumbar), type of Ayush system, study group (treatment, comparison group) and the nature of intervention (pharmacological, non-pharmacological). Ayush interventions used for cervical and lumbar spondylosis were categorized based on the presence of a comparison group. The articles which had reported AE are presented with the number of participants who had experienced AE, description of AE, the total sample size of the study and the type of Ayush system as intervention. Proportion of AE is reported based on the studies that reported AE among all the studies. They were characterized based on the information of research mandates such as registration with Clinical Trials Registry, Approval from Human ethics committee and the information on informed consent process.

Ethics approval

Ethics committee review is exempted for conducting systematic reviews as per India's National ethical guidelines for biomedical and health research involving human participants [19].

Results

We retrieved 27819 articles through an initial search from databases and other portals. We excluded duplicate articles during the screening. In the course of title and abstract screening, we excluded the articles based on the selection criteria. After the full article screening, we included 113 studies for the final analysis and qualitative synthesis, as per the PRISMA flowchart (Fig. 1).

General characteristics of included studies

General characteristics of the included articles such as the year of publication, study population, study design, type of intervention, size of the study sample and basic information on AE type are presented (Table 1). Publication of Ayush studies on cervical and lumbar spondylosis (CS and LS) was from 1976 to 2021. The number of publication is very less from 1976 to 2005. It gradually increased from 2006 and reached a peak in 2012. With a sudden dip in 2014 and an increase in 2015, followed by a reduction after 2019 (Supp Fig. 2). Majority (95%) of the selected 113 studies were interventional studies and included 77 (68.1%) journal articles and 35 (31%) academic dissertations. Among the interventional studies, 52% ($n=59$) were RCT, and remaining (43%) were non-RCT studies. Observational studies included, single case series (0.9%) and five (4.4%) case reports. Majority (82%) of the studies were conducted in India. Among the Ayush systems, 32.7% was from Ayurveda, followed by Yoga (22.1%), Siddha (24.8%), Unani (15.9%) and Homoeopathy (4.4%). Almost three-fourths of the studies were on lumbar spondylosis [65%; $n=74$], followed by cervical spondylosis (31%; $n=35$), and the remaining four included both. Interventional studies included higher number of study participants (range 10–313) than the observational studies (range = 1 and 10). Most of the studies (84.1%) include both gender. About 45 (39.8%) studies used one intervention, 27 (23.9%) two, 11(9.7%) three, 12 (10.6%) four and 18 (15.9%) used more than four interventions for either cervical or lumbar spondylosis (Table 2).

In terms of blinding in the intervention studies, 21 (18.6%) were single blinded and four with double and one study with triple blinding. Other 87 (77%) studies did not involve masking (Supp Table 6).

Of the studies included, 30 (26.5%) had a comparison group (Supp Table 7) and 104 (92%) were hospital-based and couple of studies were community-based. Most of the studies ($n=103$; 91.2%) were single-centre based and five were multi-centric studies. Informed consent-related details were available for 82 (72.6%) studies. Three-fifths ($n=71$) of the studies did not provide any facility/provision/plan to report AE (Supp Table 6). Of the total studies, 29 (25.6%) were registered with Clinical Trials Registry, 68 (60.2%) were mentioned about the ethics committee approval and 44 (38.9%) studies had declared for no conflict interest, 69 (61.1%) studies did not mention the conflict of interest (Supp Table 9).

Table 1 Characteristics of selected articles ($n=113$)

Author, year	Type of publication	Country	Population	Study design	Ayush system	Intervention	Sample size	Age (Mean ± SD/range)	Other medications	Facility/ to report AE	AE
Groessl, [23]	JA	USA	LS	RCT	Y	Non-pharma	152	53.4 ± 13.3	Yes	Yes	Yes
Michalsen, [20]	JA	Germany	CS	RCT	Y	Non-pharma	77	18–60 years	NM	Yes	Yes
Saper, [28]	JA	USA	LS	RCT	Y	Non-pharma	30	44.0 ± 12.0	Yes	Yes	Yes
Zarekar, [34]	JA	India	LS	RCT	A	Combined	50	< 35 years	NM	NM	No
Cramer, [21]	JA	Germany	CS	RCT	Y	Non-pharma	51	47.8 ± 10.4	Yes	NM	Yes
Yadaiah, [35]	JA	India	LS	RCT	A	Pharma	124	10–89 years	NM	NM	No
Williams, [22]	JA	USA	LS	RCT	Y	Non-pharma	90	48.0 ± 1.2	Yes	NM	Yes
Colgrove, [36]	JA	USA	LS	QET	Y	Non-pharma	10	45.6 ± 14.6	NM	Yes	No
Haldavnekar, [37]	JA	India	LS	QET	Y	Non-pharma	40	44.1 ± 13.3	NM	NM	No
Joshi, [38]	JA	India	LS	OPRT	A	Combined	32	40–70 years	NM	NM	No
Williams, [25]	JA	USA	LS	RCT	Y	Non-pharma	60	23–67 years	Yes	NM	Yes
Kumar, [39]	JA	Germany	LS	RCT	A	Non-pharma	64	18–70 years	NM	Yes	No
Hanan, [40]	JA	Saudi Arabia	LS	QET	U	Non-pharma	30	35.6 ± 8.8	NM	NM	No
Nair, [41]	JA	India	LS	RCT	A	Pharma	40	11–70 years	NM	NM	No
Nair, [42]	JA	India	LS	RCT	A	Pharma	68	17–70 years	NM	NM	No
Singh, [43]	JA	India	LS	RCT	U	Combined	40	20–60 years	NM	Yes	No
Mahanta, [44]	AD	India	LS	Clinical study	A	Combined	77	30–70 years	NM	NM	No
Sherman, [27]	JA	America	LS	RCT	Y	Non-pharma	228	48.4 ± 9.8	Yes	Yes	Yes
Rae, [45]	JA	USA	LS	RCT	Y	Non-pharma	20	18–89 years	Yes	NM	No
Saper, [28]	JA	USA	LS	RNT	Y	Non-pharma	320	18–64 years	Yes	Yes	Yes
Tilbrook, [46]	JA	UK	LS	RCT (parallel group)	Y	Non-pharma	313	18–65 years	Yes	Yes	Yes
Stam, [30]	JA	England	LS	RCT	H	Pharma	161	18–65 years	NM	NM	Yes
Jadhav, [47]	JA	India	Both	RCT	A	Pharma	100	21–65 years	NM	NM	No
Ansari, [48]	JA	India	LS	RCT	U	Combined	60	25–50 years	NM	NM	Yes
Aafreen, [49]	JA	India	LS	Controlled CT	U	Pharma	42	37.8 ± 9.3	NM	Yes	No
Lari, [50]	JA	India	LS	RCT	U	Combined	60	20–60 years	NM	NM	No
Tekur, [51]	JA	India	LS	RCT	Y	Non-pharma	80	18–60 years	NM	NM	No
Smeeta, [52]	JA	India	CS	RCT	A	Combined	30	35–45 years	NM	NM	No
Tekur, [53]	JA	India	LS	RCT	Y	Non-pharma	80	18–60 years	NM	NM	No
Neyaz, [29]	JA	India	LS	RCT	Y	Non-pharma	70	18–55 years	Yes	NM	Yes
Michalsen, [26]	JA	Germany	LS	RCT	Y	Non-pharma	68	18–75 years	Yes	Yes	Yes
Monro, [54]	JA	India	LS	RCT	Y	Combined	61	20–45 years	Yes	NM	No
Sharma, [55]	JA	India	LS	RCT	A	Pharma	60	36–45 years	NM	NM	No
Tausif, [56]	JA	India	CS	RCT	U	Non-pharma	50	46.6 ± 8.9	NM	NM	No

Table 1 (continued)

Author, year	Type of publication	Country	Population	Study design	Ayush system	Intervention	Sample size	Age (Mean ± SD/range)	Other medications	Facility/ to report AE	AE
Deepak, [57]	JA	India	LS	RCT	A	Pharma	40	20–60 years	NM	NM	No
Morone, [58]	JA	USA	LS	RCT	Y	Non-pharma	40	> 65 years	Yes	NM	No
Sharma, [59]	JA	India	LS	RCT	A	Pharma	30	20–70 years	NM	NM	No
BethHighland, [60]	JA	USA	LS	Pilot RCT	Y	Combined	68	44.3 ± 12.7	Yes	NM	No
Hepburn, [61]	AD	South Africa	CS	CCT	H	Pharma	50	36.1 years	Yes	NM	Yes
Kumar, [62]	JA	India	LS	Open randomized Parallel group trial	A	Combined	38	25–65 years	NM	NM	No
Sheeraz, [63]	JA	India	LS	OPRT	U	Non-pharma	40	31–70 years	No	NM	No
Sawarkar, [64]	JA	India	CS	PRT	A	Pharma	30	20–60 years	Yes	NM	No
Kumari, [65]	JA	India	LS	RCT	A	Pharma	34	20–60 years	NM	NM	No
Nandini, [66]	JA	India	CS	PRT	Y	Combined	60	24–56 years	NM	NM	No
Telles, [67]	JA	India	LS	PRT	Y	Non-pharma	40	20–45 years	Yes	Yes	No
Baig, [68]	JA	India	CS	RCT	U	Combined	33	21–60 years	NM	NM	No
Mungara, [69]	JA	India	LS	RCT	A	Pharma	45	20–60 years	NM	NM	No
Suman, [70]	JA	India	LS	RCT	A	Pharma	30	20–60 years	NM	NM	No
Subbuthai, [71]	AD	India	LS	Open labelled RCT	U	Pharma	40	20–60 years	NM	Yes	No
Rai, [72]	JA	India	LS	RCT	A	Combined	30	40–70 years	NM	NM	No
Sharma, [73]	JA	India	LS	RCT	A	Pharma	30	18–50 years	NM	NM	No
Evangeline, [74]	AD	India	CS	RCT	S	Pharma	40	20–60 years	No	Yes	No
Gupta, [75]	AD	India	LS	RCT	A	Pharma	108	18–60 years	NM	Yes	No
Brintha, [76]	AD	India	LS	Prospective RCT	S	Pharma	40	31–60 years	NM	Yes	No
Lubana, [77]	AD	India	CS	Prospective RCT	S	Pharma	40	20–60 years	NM	Yes	No
Prasad, [78]	AD	India	CS	RCT	A	Combined	40	20–69 years	NM	Yes	No
Tekur, Padmini [79]	AD	India	LS	Randomized Crossover controlled study	Y	Non-pharma	80	18–60 years	NM	Yes	No
Dunleavy, [80]	JA	USA	CS	Quasi-randomized parallel controlled study	Y	Non-pharma	88	55.6 ± 9.0	Yes	NM	No
Kendre, [81]	AD	India	LS	RCT	A	Pharma	200	> 60 years	NM	NM	No
Niranjana, [82]	AD	India	CS	Non-RCT	S	Combined	40	25–70 years	NM	Yes	No
Kalaivani, [83]	AD	India	CS	CT	S	Pharma	40	20–60 years	NM	Yes	No
Rajanandhini, [84]	AD	India	CS	CT	S	Combined	60	20–60 years	NM	Yes	No
Prakash, [85]	AD	India	LS	CT	S	Pharma	40	30–60 years	NM	Yes	No
Sathyakala, [86]	AD	India	CS	CT	S	Combined	40	21–60 years	NM	Yes	No

Table 1 (continued)

Author, year	Type of publication	Country	Population	Study design	Ayush system	Intervention	Sample size	Age (Mean ± SD/range)	Other medications	Facility/ to report AE	AE
Prathiba, [87]	AD	India	CS	CT	S	Pharma	60	21–60 years	NM	Yes	No
Pasupathy, [88]	AD	India	CS	Non-RCT	S	Combined	40	30–60 years	NM	NM	No
Jeyabharathi, [89]	AD	India	CS	CT	S	Combined	40	31–70 years	NM	NM	No
Venkatachalam, [90]	AD	India	CS	CT	S	Combined	40	31-above 70 years	NM	NM	No
Elakkia, [91]	AD	India	CS	CT	S	Combined	40	21–60 years	NM	Yes	No
Devi, [92]	AD	India	CS	CT	S	Combined	40	21–60 years	NM	Yes	No
Malarvizhi, [93]	AD	India	LS	CT	S	Combined	40	21–60 years	NM	Yes	No
Devi, [94]	AD	India	LS	CT	S	Pharma	40	20–60 years	NM	Yes	No
Manju, [95]	AD	India	LS	CT	S	Pharma	40	21– > 60 years	NM	NM	No
Shalini, [96]	JA	India	CS	Open label trial	A	Pharma	10	18–70 years	NM	NM	No
Pradhan, [97]	JA	India	LS	CT	A	Pharma	60	< 20- > 60 years	NM	NM	No
Jain, [98]	JA	India	CS	OS	Y	Non-pharma	44	45.6 ± 8.3	NM	NM	No
Devi, [99]	AD	India	CS	Open CT	S	Pharma	40	21–50 years	NM	Yes	No
Mallinath, [100]	AD	India	LS	CT	A	Pharma	100	20–60 years	NM	NM	No
Deebiga, [101]	JA	India	LS	Case study	S	Pharma	1	44 years	NM	NM	No
Mishra, [102]	JA	India	LS	Case controlled CT	A	Pharma	30	20–60 years	NM	NM	No
Prakash, [103]	JA	India	LS	Case study	A	Pharma	1	49 years	NM	NM	No
Kumari, [104]	JA	India	LS	Case study	A	Combined	1	24 years	NM	NM	No
Siddiqui, [105]	JA	India	CS	OCS	U	Non-pharma	30	20–60 years	NM	NM	No
Ansari, [31]	JA	India	LS	Case study	U	Combined	1	23 years	No	NM	No
Rao, [106]	JA	India	Both	Clinical study	A	Pharma	40	20–70 years	NM	NM	No
Sharma, [107]	JA	India	CS	PIS	A	Pharma	60	30–65 years	NM	NM	No
Shah, [108]	JA	India	LS	Non-randomized PIS	H	Pharma	20	40–55 years	NM	NM	No
Shaikh, [109]	JA	India	LS	CT	U	Non-pharma	20	40–60 years	NM	Yes	No
Pandey, [110]	JA	India	CS	Open label trial	A	Pharma	10	> 18 to < 70 years	NM	NM	No
Ghufran, [111]	JA	India	CS	CT	U	Pharma	15	21–60 years	NM	NM	No
Yousuf, [112]	JA	India	LS	Interventional OS	U	Pharma	60	> 20– < 50 years	NM	NM	No
Rajashri, [113]	AD	India	CS	CT	S	Pharma	40	21–70 years	NM	NM	No
Selvi, [114]	AD	India	LS	CT	S	Combined	40	20–60 years	NM	Yes	No
Usha, [115]	AD	India	LS	CT (pilot study)	S	Pharma	40	31–60 years	NM	Yes	No
Tarique, [116]	JA	India	LS	OCS	U	Non-pharma	30	25–60	NM	Yes	No
Patil, [117]	JA	India	LS	CT	Y	Non-pharma	12	36.8 ± 3.8	NM	Yes	No
Paresh, [118]	JA	India	LS	CT	A	Pharma	20	20–80 years	NM	NM	No

Table 1 (continued)

Author, year	Type of publication	Country	Population	Study design	Ayush system	Intervention	Sample size	Age (Mean ± SD/range)	Other medications	Facility/ to report AE	AE
Sharma, [119]	JA	India	Both	PCT	A	Pharma	50	40.5 ± 11.3	NM	NM	No
Ileana, [120]	JA	Romania	LS	CT	H	Combined	20	20–86 years	NM	NM	No
Ahmad, [121]	JA	India	LS	Case series	U	Combined	3	38, 29, 64 years	NM	Yes	No
Kumar, [122]	AD	India	CS	Pilot study	S	Combined	40	21–60 years	NM	Yes	No
Bharati, [123]	JA	India	LS	OCT (pilot study)	A	Pharma	27	18–70 years	NM	NM	No
Nilopher, [124]	AD	India	CS	OCT	S	Combined	40	20–60 years	NM	Yes	No
Urooj, [32]	JA	India	Both	Comparative open CT	U	Non-pharma	98	20-60 years	NM	NM	Yes
Sreedhana, [125]	AD	India	LS	OCCT	S	Combined	60	30–60 years	NM	Yes	No
Rasakumar, [126]	AD	India	CS	OCT	S	Combined	60	20–60 years	NM	Yes	No
Madhavikutty, [127]	JA	India	LS	Comparative CT	A	Pharma	330	12–70 years	NM	NM	No
Sharma, [128]	JA	India	CS	ROCS	A	Pharma	48	18–70 years	No	NM	No
Khan, [129]	JA	India	CS	Controlled CT	U	Combined	34	15—60 years	NM	NM	No
Thakur, [130]	IAR	India	LS	Case study	H	Combined	10	36.2 ± 11.1	No	NM	No
Muthumari, [131]	AD	India	LS	Before-after studies	S	Pharma	20	18–60 years	NM	Yes	No
Bhatted, [132]	JA	India	LS	Case study	A	Pharma	1	59 years	NM	NM	No
Aarthy, [133]	AD	India	LS	OCT	S	Combined	40	20–60 years	NM	Yes	No

JA journal article, *AD* academic dissertation, *CS* cervical spondylosis, *LS* lumbar spondylosis, *A* Ayurveda, *Y* Yoga and Naturopathy, *U* Unani, *S* Siddha, *H* Homoeopathy, *RCT* randomized controlled trial, *QET* quasi-experimental trial, *OPRT* open prospective randomized trial, *CT* clinical trial, *CCT* comparative clinical trial, *PRT* parallel randomized trial, *OS* observational study, *OCS* observational clinical study, *PIS* prospective interventional study, *PCT* prospective clinical trial, *OCT* open clinical trial, *OCCT* open comparative clinical trial, *ROCS* retrospective observational cohort study, *Pharma* pharmacological, *Non-Pharma* non-pharmacological, *NM* not mentioned

Studies with a comparison group

Of the 30 studies with a comparison group, six were conducted for cervical spondylosis (CS) and the remaining for lumbar spondylosis (LS). Of the six CS studies, four used Yoga and one study each with Unani and Homoeopathy interventions. In 16 studies, the LS participants were given Yoga as intervention followed by Ayurveda (4 studies) and Unani (3 studies) and a single study with Homoeopathy (Supp Table 7).

Studies without a comparison group

Of the 83 studies without any comparison group, 29 (34.9%) were conducted for cervical spondylosis, 50 (60.2%) for lumbar spondylosis and the remaining for both the conditions. For CS, Siddha intervention was used in 17 studies (58.6%), followed by Ayurveda ($n=6$, 20.7%), Unani ($n=4$, 13.8%) and Yoga ($n=2$, 6.9%). For LS, the Ayurveda system of medicine was used in 23 studies (46%), followed by Siddha ($n=11$, 22%), Unani ($n=9$, 18%), Yoga ($n=4$, 8%) and Homoeopathy ($n=3$, 6%). Only four studies involved both cervical and lumbar spondylosis. Of them, three had Ayurveda medicine and single study with Unani intervention (Supp Table 8).

Risk-of-bias assessment among the included studies

We used RoB2 for RCT [High risk = 28 (47.5%), some concerns = 29 (49.2%) Low risk = 2 (3.4%)], ROBINS-I for non-RCT [serious = 4 (8.3%), moderate risk = 27 (56.3%), low risk = 17 (35.4%)] and JBI for case series (low risk = 5 (100%) and case studies (low risk = 1 (100%) to assess the risk of bias and they are reported (Supp Table 10-Table 14)

Adverse events

Of the 113 studies, 15 (13.3%) reported and described AE and these included report from Yoga ($n=11$) and two each from Unani and Homoeopathy systems. Eleven of these reports were from lumbar spondylosis and three from cervical spondylosis. A single report was about both cervical and lumbar spondylosis. Of the AE reports, 12 were from non-pharmacological interventions and two were based on pharmacological intervention and a single study report was from combined intervention (Table 3). The number of study participants who experienced any kind of adverse event from the 15 studies ranges from a minimum of 1 to a maximum of 49. Description of intervention such as type and duration of intervention, method of providing the intervention, presence of self-practice for yoga intervention, description of adverse events including, number of participants reported AE, type and description of AE for the 15 studies are provided (Table 4).

Table 2 Basic description of selected articles ($n=113$)

Characteristics	*n* (%)
Type of publication	
Journal article	77 (68.1)
Academic dissertation	35 (31.0)
Institutional annual report	1 (0.9)
Country	
India	93 (82.3)
USA	12 (10.6)
Germany	4 (3.5)
England	1 (0.9)
Romania	1 (0.9)
Saudi Arabia	1 (0.9)
United Kingdom	1 (0.9)
Ayush system	
Ayurveda	37 (32.7)
Yoga	25 (22.1)
Unani	18 (15.9)
Siddha	28 (24.8)
Homoeopathy	5 (4.4)
Study population	
Cervical spondylosis	35 (31.0)
Lumbar spondylosis	74 (65.5)
Both	4 (3.5)
Type of intervention	
Pharmacological	48 (42.5%)
Non-Pharmacological	30 (26.5%)
Combined	35 (31.0%)
Study design	
Interventional study	107 (94.7)
Observational study	6 (5.3)
Sample size (range)	
Interventional study	10–313
Observational study	1–10
Gender	
Male	4 (3.5)
Female	3 (2.7)
Both	95 (84.1)
Not reported	11 (9.7)
Number of interventions	
One	45 (39.8)
Two	27 (23.9)
Three	11 (9.7)
Four	12 (10.6)
More than four	18 (15.9)

Low back pain, muscle soreness, transient worsening of neck pain or muscle soreness, transient limb pain, migraine and vertigo were reported by the CS

Table 3 Proportion of studies reported any kind of adverse events ($n=113$)

Characteristics	*n* (%)
Ayush system	
Ayurveda	0 (0)
Yoga	11 (9.7)
Unani	2 (1.8)
Siddha	0
Homoeopathy	2 (1.8)
Study population	
Cervical spondylosis	3 (2.7)
Lumbar spondylosis	11 (9.7)
Both	1 (0.9)
Intervention type	
Pharmacological	2 (1.8)
Non-pharmacological	12 (10.6)
Combined	1 (0.9)

participants with yoga intervention [20, 21]. Exacerbated/increased level of back pain, transient worsening of low back pain, herniated disc, increased back pain possibly or probably related to yoga, increased back pain unrelated to yoga, other pain probably related to yoga, accident/injury, increase of an already existing tinnitus, slightly increased dizziness and headache, increased back pain, herniated disk, increased back pain, increased pain, mild self-limited joint and back pain and slight increased pain reported by the LS participants with yoga interventions [22–29]. One death due to accident was reported during the intervention in the study by Tilbrook [46]. Headache, aggravation of neck pain and lethargy was reported by CS participants who were taking homoeo intervention [61]. Another homoeo study for LS mentioned that it had adverse events, adverse drug reactions, adverse events, adverse drug reactions, however they were not described in detail [30]. Fainting (vaso-vagal shock) was reported in an Unani intervention for LS [31] and ecchymosis was mentioned in an Unani for both cervical and lumbar spondylosis [32].

Withdrawal of study participants

Of the 113 studies, 32 (28.3%) had reported withdrawal of participants ($n=400$). Studies reporting withdrawal included nine of 37 from Ayurveda, 15 of 25 from Yoga, seven of 18 studies from Unani, one from 5 homoeopathy studies and none from 28 Siddha based studies. Among the total, 80 studies had no information on withdrawal of study participants, but one reported that there was no withdrawal during the study. Nine of 48 studies which had pharmacological interventions ($n=122$; 30.5%) and 18 of 30 non-pharmacological ($n=238$; 59.5), five of 35 studies combined interventions ($n=40$; 10%) had withdrawals. The 15 studies reported AE had withdrawals and drop outs due to various reasons. Description of intervention such as the number of participants in study groups, detailed description of intervention with name of pharmacological and non-pharmacological intervention, number of follow-ups and the timeline, number of withdrawal and dropouts and reasons for the same for the 15 studies are provided (Table 5).

Discussion

In the current review, we synthesized the adverse events following Ayush interventions (pharmacological and/or non-pharmacological) for cervical and lumbar spondylosis. In this review of predominantly interventional studies from published literature mostly conducted in India, one in eight of the studies had reported adverse events.

Studies reporting AEs mainly used Yoga as an intervention, and a couple of studies used Homoeopathy or Unani interventions. Among the Ayush systems, none of the Siddha or Ayurveda studies reported any adverse events for cervical and lumbar spondylosis treatment. When compared to cervical spondylosis, more AEs were reported by lumbar spondylosis participants. Although all the reviewed studies mentioned in the objective statement or in the methods section that they would observe and record the AEs, only one-sixth of them described the adverse events. This could lead to considerable underreporting of AE among the Ayush studies for cervical and lumbar spondylosis.

Besides, our review of abstract reports and published documents from the Country's pharmacovigilance centres at different levels (National; Intermediary and Peripheral) for Ayush systems did not yield any AE documentation for Ayush interventions [33]. The practitioners, researchers did not use these centres for reporting. Another reason for underreporting may be that more academic dissertations were included in this study. There may be a lack of vigilant reporting of AE by scholars.

The strength of our systematic review is that, according to the best of our knowledge, this may be a maiden attempt to document and synthesize evidence for adverse events of Ayush interventions for lumbar and cervical spondylosis. There are some limitations in this systematic review. There was a difficulty to search the articles for Ayush systems of medicine as majority of the articles are published in non-indexed journals, and moreover the Ayush databases (Ayush research portal, DHARA, and Shodhganga) are not compatible to use structured search strategy. This estimation of AE may result from the bias and limitations of the original studies included in the qualitative synthesis. For instance, majority of the included RCTs suffered from high or moderate risk of

Table 4 Description of adverse events among the studies reported with any type of adverse events (15 studies, 164 participants)

Author, year	Population	System	Age in years (range; mean ± SD)	Intervention					Study group and size	Adverse events		
				Type	Description	Duration	Yoga sessions handled by	Self-practice		# of participants reported AE	Type of AE	Description of AE
Michalsen et al. [12]	CS	Yoga	18–60	NP	Iyengar yoga	9 weeks, 90 min/week	Certified instructor; physician assistant	Yes	Yoga–38	1 Some patients	Not categorized	Low back pain Muscle soreness
									Exercise–39	0	–	–
Cramer, [21]	CS	Yoga	19–60; 47.8 ± 10.4	NP	Iyengar yoga	9 weeks, 90 min/week	Certified instructor, physiotherapist	Yes	Yoga–25	9	Not categorized	Transient worsening of neck pain or muscle soreness
										3	Minor adverse effect	Transient limb pain, Migraine and vertigo
									Exercise–26	8	Not categorized	Transient worsening of neck pain or muscle soreness
										2	Minor adverse effect	Transient limb pain, Migraine and vertigo
Williams, [22]	LS	Yoga	18–70; 48.0 ± 1.2	NP	Iyengar yoga	24 weeks, 90 min/twice a week	Certified instructor assistants	Yes	Yoga–43	1	Adverse event	Yoga exacerbated LBP
									SMC–47			
Hepburn [61]	CS	Homoeopathy	18–65; 36.1	P	Homoeopathic medicine	7 days, 3 times/day	NA	NA	Traumeel S and placebo Piroxicam- 25	4	Not categorized	Headache
										2		Aggravation of neck pain
										2		Lethargy
									Piroxicam and placebo Traumeel S–25	2		Headache
										1		Aggravation of neck pain

Table 4 (continued)

Author, year	Population	System	Age in years (range; mean ± SD)	Intervention					Study group and size	Adverse events		
				Type	Description	Duration	Yoga sessions handled by	Self-practice		# of participants reported AE	Type of AE	Description of AE
Groessl et al. [23]	LS	Yoga	53.4 ± 13.3	NP	Hatha yoga	12 weeks, 60 min/twice a week	Certified instructor	Yes	Yoga–76	1	Adverse events	Increased level of back pain
										1		Back went out
									Delayed Treatment–76			
Saper et al. [28]	LS	Yoga	44.0 ± 12.0	NP	Hatha yoga	12 weeks, four 3 week segments each 75 min	Yoga instructors	Yes	Yoga–30	1	Not categorized	Transient worsening of low back pain
									Usual care–30			
Williams et al. [25]	LS	Yoga	23–67; Yoga group: 48.7 ± 10.6 Educational control group: 48.0 ± 1.96	NP	Iyengar yoga	16 weeks, 1.5 h/week	One yoga instructor	Yes	Yoga–30	1	Adverse event	Herniated disc***
									Education–30			
Tilbrook et al. [46]	LS	Yoga	18–65; Yoga group: 46.3 ± 11.5 Usual care group: 46.4 ± 11.3	NP	Not available	75 min/week	20 yoga teachers (10 each from British Wheel of Yoga and Iyengar Yoga)	Yes	Yoga–156	1	Serious adverse event	Increased back pain possibly or probably related to Yoga
										1	Nonserious adverse event	Accident/ injury*
										4		Increased back pain possibly or probably related to Yoga
										3		Increased back pain unrelated to Yoga
										3		Other pain probably related to Yoga**
									Usual care–157	1	Serious adverse event	Accident/ injury*
										1		Death

Table 4 (continued)

Author, year	Population	System	Age in years (range; mean ± SD)	Intervention					Study group and size	Adverse events		
				Type	Description	Duration	Yoga sessions handled by	Self-practice		# of participants reported AE	Type of AE	Description of AE
Michalsen et al. [26][1]	LS	Yoga	18–75; 55 ± 10	NP	Jyoti meditation	8 weeks, 90 min/week	Information not available	Yes	Meditation–32	2	Not categorized	Increase of an already existing tinnitus
									Exercise–36	1		Slightly increased dizziness and headache
Sherman et al. [27]	LS	Yoga	48.4 ± 9.8	NP	Viniyoga	12 weeks, 75 min/week	Yoga instructor physical therapists	Yes	Yoga–87	13	Mild/moderate adverse event	Increased Back pain
										1	Not categorized	Herniated disk
									CSE–75	13	Mild/moderate adverse event	Increased Back pain
									Self-care book–45	1	Not categorized	Increased pain
Saper et al. [28]	LS	Yoga	18–64; Yoga group: 46.4 ± 10.4; physical therapy: 46.4 ± 11.1; education: 44.2 ± 10.8	NP	Yoga	12 weeks, 75 min/week	Yoga instructors	Yes	Yoga–127	9	Adverse events	Mild self-limited joint and back pain
									Physical therapy–129	14		
									Education–64	1		
Stam et al. [30][#]	LS	Homoeopathy	18–65; SRL group: 40.6 ± 13.6; CCC group: 41.0 ± 12.8	P	Homoeopathic gel	1 week; 3 gm/day; 3 times a day	NA	NA	SRL–83	9	Adverse events	Not reported
										3	Adverse drug reactions	
									CCC–78	19	Adverse events[$]	
										18	Adverse drug reactions	

Table 4 (continued)

Author, year	Population	System	Age in years (range; mean ± SD)	Intervention					Study group and size	Adverse events		
				Type	Description	Duration	Yoga sessions handled by	Self-practice		# of participants reported AE	Type of AE	Description of AE
Ansari et al. [48]	LS	Unani	25–50	C	Unani formulation and cupping therapy	30 days, cupping-3 times/day; internal medicine 2 times/day	NA	NA	Habb-e-Asgandh & Habb-e-Suranjan–30			
									Wet cupping therapy–30	2	Side effect	Fainting (vasovagal shock)
Neyaz et al. [29]	LS	Yoga	18–55; 35.8 ± 10.6	NP	Hatha yoga	12 weeks, 35 min/week	One trained yoga therapist	Yes	Yoga–35	3	Nonserious side effects	Slight increased pain
									CTE–35			
Urooj et al. [32][┐]	Cervical OA	Unani	20–60	NP	Cupping therapy	4 consecutive days, 20 min/sitting	NA	NA	Group A–33	2	Not categorized	Ecchymosis
	Lumbar OA								Group B–33			
	Knee OA								Group C–32			

P pharmacological, *NP* non-pharmacological, *C* combined, *AE* adverse events, *CS* cervical spondylosis, *LS* lumbar spondylosis, *OA* osteoarthritis, NA not applicable, *SMC* self-directed standard medical care, *CSE* conventional stretching exercises, *SRL* Sprioflor gel, *CCC* Cremor Capsici Compositus, *CTE* conventional therapeutic exercises

[#] 4 ADRs in the CCC were rated 'severe' compared to none of the ADRs in the SRL group

[*] Unrelated to intervention

[**] All patients had a history of other pain

[***] Participant with symptomatic osteoarthritis

[$] Out of 19 subjects in CCC group, one subject who experienced two AEs

[┐] Adverse event was not reported in which group

Table 5 Description of intervention and withdrawals for the studies reported with AE

Author, year, country	Intervention description	Follow-up	# Withdrawals and reason
Cramer et al. [21] Germany	**Yoga group (*n* = 25)**: Iyengar yoga [Bharadvaja's twist, Bridge pose, Corpse pose, Downward facing dog, Downward facing hero, Extended side angle, Extended triangle, Mountain pose, Prosperous pose, Reclining big toe, Standing half forward bend (at wall), Thunderbolt pose, Upward hand pose, Warrior pose II];	Baseline; at 12 weeks; at 24 weeks	Yoga group (*n* = 3): 1-Symptom worsening, 1-Acute illness, 1-Scheduling problems
	Exercise group (*n* = 26) Self-care manual designed by a large Statutory German Health insurance company to relieve neck pain and stiffness	Baseline; at 12 weeks; at 24 weeks	Exercise group (*n* = 0)
Williams et al. [22] USA	**Yoga group (*n* = 43):** Iyengar yogaSavasana II Supine; Savasana prone; Supta padangusthasana II prone; Supta tadasana; Supta urdhva hastasana; Supta padangusthasana I and II; Supta pavanmuktasana; Urdhva prasarita padasana at the wall; Pavanmuktasana-over bolster on 2 chairs; Parsava pavanamuktasana: Utthita hasta padangusthasana I and II; Ardha uttanasana; Uttanasana; Adho mukha svanasana; Tadasana; Urdhva hastasana; Utthita padmasana; Utthita hasta padasana*; Parsva hasta padasana*; Utthita parsvakonasana*; Utthita trikonasana*; Virabhadrasana II*; Ardha chandrasana*; Prasarita padottanasana; Parsvottanasana; Parsvottanasana; Parivrtta trikonasana*; Bharadvajasana-seated on chair; Utthita Marichyasana; Dandasana; Marichyasana III; Adho mukha virasana-with bolster under abdomen. (*with support of upper wall rope)		
	Standard medical care group (*n* = 47): Continued self-directed standard medical care, no attempt was made to regulate treatment received. Participants were waitlisted and offered the yoga classes 6 months after the conclusion of the study		
Hepburn, [61], Canada	**Group 1 (*n* = 25):** Traumeel S sachets and placebo Piroxicam (corn starch); *Placebo:* 40 mg (2 × 20 mg capsules) orally for the first two days, followed by 20 mg (1 × 20 mg capsule) daily orally for the following 5 days *Traumeel S:* One tablet to be sucked 3 times a day for 7 days	At day 1; at day 3; at day 7	Drop outs (*n* = 10) [3-Took medication during the trial which would affect results, 1-Missed appointment on day three, 6-Missed appointment on day seven]
	Group 2 (*n* = 25): Piroxicam and placebo Traumeel S (Lactose powder); *Piroxicam:* 40 mg (2 × 20 mg capsules) orally for the first two days, followed by 20 mg (1 × 20 mg capsule) daily orally for the following 5 days. *Placebo:* One tablet to be sucked 3 times a day for 7 days		

Table 5 (continued)

Author, year, country	Intervention description	Follow-up	# Withdrawals and reason
Groessl et al. [23] , USA	**Yoga group (*n* = 76):** Hatha yoga; Physical yoga postures, movement sequences, and regulated breathing. Directed attention and brief meditation	Baseline; at 6 weeks; at 12 weeks; at 6 months	Yoga group (*n* = 28) [1-withdrew from study, 7-work conflict, 8-transportation, 1-no reason given, 4-non yoga injury, 3-other medical, 2-homeless, 1-back pain, 1-type of yoga]
	Delayed treatment group (*n* = 76): Attend the yoga intervention after 6 months		Delayed treatment group (n = 4) [1-withdrew from study, 3-did not wait 6 months to use yoga]
Williams et al. [25], USA	**Yoga group (*n* = 30):** Hatha yoga Svasana relaxation and breathing exercises*, Knee to chest*, Knee to chest with twist*, Pelvic clocks*, Cat and dog pose (and modifications)*, Chair pose (and modified)*, Mountain pose*, Shoulder opener*, Half moon*, Child's pose*, Reclining cobbler*, Downward-facing dog (and modified at wall)*, Triangle pose at wall, Locust pose, Reclining big toe pose, Warrior I pose, Downward-facing dog, Lunge with wall assist, Standing squat with half forward bend, Baby dancer pose, Deep lunge, Spinal rolls, Svasana relaxation and breathing exercises*. Each class began and ended with Svasana, a relaxation exercise. (* Exercises included on the audio CD provided to participants for home practice)	Pre-intervention, post-intervention, 3-month follow-up	Yoga intervention group: At 16 weeks (*n* = 10) [3-no shows after baseline, 3-quit, 1-adverse event, 2-medically ineligible, 1-unwilling to perform active postures]; After 3 months follow-up (*n* = 0)
	Usual care group (*n* = 30): Continued to receive their routine medical care and medications. Offered yoga interventions after 26 weeks		Educational control group: At 16 weeks (*n* = 6) [3-lost to follow-up, 2-ineligible due to other CAM use for CLBP, 1-no show at baseline]; After 3 months follow-up (n = 2) [1- lost to follow-up, 1-died]
Tilbrook et al. [46], UK	**Yoga group (*n* = 156):** Asana, pranayama, relaxation techniques, mental focus, and philosophy. Classes consisted of an introduction to the weekly theme; pain-relieving or settling-in relaxing poses; a program of seated, standing, prone, and supine poses; educative postural advice; and 5 to 15 min of relaxation	Baseline; at 3 months; at 6 months; at 12 months	Yoga group: At baseline (*n* = 4) [1-lost to follow-up at baseline, 2-did not want to continue, 1-questionnaire not returned]; At 3 months (n = 21) [5-lost to follow-up,3-did not want to continue, 3- ineligible after randomization, 1-unable to attend classes, 8-questionnaire not returned, 1-change from baseline scores could not calculated); At 6 months (*n* = 19) [6-lost to follow-up, 4-did not want to continue, 3- deemed ineligible after randomization, 1-unable to attend classes, 4-questionnaire not returned, 1-change from baseline scores could not calculated]; At 12 months (*n* = 21) [13-lost to follow-up, 4-did not want to continue, 3- deemed ineligible after randomization, 1-unable to attend classes]
	Usual care group (*n* = 157): Offered a 1-time session of yoga after final follow-up		

Table 5 (continued)

Author, year, country	Intervention description	Follow-up	# Withdrawals and reason
Michalsen et al. [26], Germany	**Focused meditation technique (Jyoti meditation) (*n* = 32):** Jyoti meditation for controlling and directing attention away from the physical body and sensations, from the emotions and thoughts to a place of relaxation or peace within the organism	Baseline; at 4 weeks; at 8 weeks	Meditation group ($n = 12$) [1-health problem, 8-non-compliance, 3-did not participate at all]
	Exercise group (*n* = 36): A total of 15 exercises were described focusing on muscle stretching, strengthening and joint mobility with proper posture depiction		Exercise group ($n = 4$) [1-health problem, 3- non-compliance]
Sherman et al. [27], USA	**Yoga group (*n* = 87):** Viniyoga, and included 17 relatively simple postures, with variations and adaptations. Each class included breathing exercises, 5 to 11 postures (lasting approximately 45–50 min), and guided deep relaxation. Six distinct and progressive classes were taught in pairs	Baseline; at 6 weeks; at 12 weeks; at 26 weeks	Yoga group ($n = 5$ [sickness, family emergency, time conflict]
	Stretching group (*n* = 75): Aerobic exercises, 10 strengthening exercises, and 12 stretches, held for 30 s each (a total of 10.5 min of stretching). Classes consisted of 15 exercises designed to stretch the major muscle groups but emphasizing the trunk and legs (a total of 52 min of stretching), and 4 strengthening exercises		Exercise group ($n = 5$) [sickness, family emergency, time conflict]
	Self-care group (*n* = 45): Self-care book; Self-care participants received the Back Pain Helpbook, which provides information on the causes of back pain and advice on exercising, making appropriate lifestyle modifications and managing flare-ups		self-care group ($n = 0$)

Table 5 (continued)

Author, year, country	Intervention description	Follow-up	# Withdrawals and reason
Saper et al. [28], USA	**Yoga group (*n* = 127):** Hatha yoga group: Svasana Relaxation/ Breathing Exercise; Knee to Chest*; Knee Together Twist*; Shoulder Opener*; Mountain*; Chair twists, standing and seated; Cobra*; Bridge; Downward Facing dog (and at wall)*; Pelvic Tilt*; Cat and Cow*; Chair Pose*; Crescent Moon*; Reclining Cobbler*; Locust*; Child Pose*; Triangle (with and without the wall); Sphinx*; Standing forward bend at wall*; Extended Leg*; Warrior*; Sun salutations; Baby Dancer*; Spinal Rolls; Svasana Integrative Relaxation (* These exercises were included in the home practice videos provided to participants)	Baseline; at 26 weeks; at 40 weeks; at 52 weeks	Yoga group: Treatment phase (*n* = 2) [2-did not complete any follow-up surveys]; Maintenance phase (*n* = 8) [8-did not attend any treatment phase classes and were discontinued after 12 weeks]
	Physical therapy group (*n* = 129): Abdominal bracing; Bracing with heel slides; Bracing with leg lifts; Bracing with bridging; Bracing with standing; Bracing with standing; Bracing with standing row exercise; Bracing with walking; Quadruped arm lifts with bracing; Quadruped leg lifts with bracing; Quadruped alternative arm & leg lifts w/bracing; Side support with knees flexed; Side support with knees extended; Side support with knees flexed; Side support with knees extended		Physical therapy: Treatment phase (*n* = 16) [15- did not complete any follow-up surveys, 1- was found to meet exclusion criterion and was discontinued]; Maintenance phase (n = 7) [5-did not attend any treatment phase classes and were discontinued after 12 weeks, 1- was found to meet exclusion criterion and was discontinued, 1-withdrew due to an unrelated illness]
	Education (*n* = 64): Participants received the Back Pain Help Book which includes information on CLBP, self-management, stretching, strengthening, and the role of emotions an fear avoidance		Education group: Treatment phase (*n* = 3) [3-did not complete any follow-up surveys]; Maintenance phase (*n* = 0)
Ansari et al. [48] India	**GROUP A (*n* = 30)**: Habb-e-Asgandh & Habb-e-Suranjan- Unani formulation and cupping therapy. Unani formulation, i.e. Habb-e-Asgandh14 (2 T.I.D.) and Habb-e-Suranjan15 (2 T.I.D.). The medicines were given orally and the patients were advised to take them after meals	Baseline; at day15; at day 30; at day 60	No information
	GROUP B (*n* = 30): Wet cupping therapy—30; Cupping procedure on 0, 15th and 30th days on the lower part of back 3–5 cm lateral to midline at the level of L2, 3, 4 vertebrae on both sides		

Table 5 (continued)

Author, year, country	Intervention description	Follow-up	# Withdrawals and reason
Neyaz et al. [29] India	**Yoga group (*n* = 35)**: Hatha yoga: Hatha yoga: Introduction of yoga philosophy; Sithilikaran Vyayama (Flexibility practice): Supta Udarakarshanasana (folded leg lumbar stretch), Shavaudarakarshanasana (Crossed leg lumbar stretch), Supta Pawanmuktasana (leg lock pose); Yogasanas: Ustrasana (Camel pose), Bhujangasana (Cobra pose), Salabhasana (Grasshopper pose), Settubandasana (Bridge pose); Quick relaxation technique: Savasana (Corpse pose) with pranayama; Pranayama (breath control): Nadi suddhi (Alternate nostril breathing), Bhramari (Humming breathing); Medication (deep relaxation technique): Savasana (Chanting AUM or OM)	Baseline; at 6-week; at 12-week	Yoga group: At 6 weeks (*n* = 15) Lost to follow-up [13-Discontinued allocated intervention, 2-Reason-not specified); At 12 weeks (*n* = 3) [2-Shifted elsewhere,1-Pain recurred]
	Conventional therapeutic exercise group (CTE) (*n* = 35): Short introduction regarding benefits of exercises; Warm-up exercises; Hip extensors strengthening both sides, Hamstring stretching both sides, Rectus abdominis strengthening, Erector spinae stretching, Erector spinae strengthening, Pyriformis stretching both sides, Oblique abdominal muscle strengthening both sides, Hip abductor strengthening both sides; Relaxation		Exercise group: At 6 weeks (*n* = 12) Lost to follow-up [11- Discontinued allocated intervention, 1-Reason not specified); At 12 weeks (*n* = 5) [2-Shifted elsewhere, 1- ill health, 2-Too busy]
Urooj et al. [32] India	**Group A (cervical osteoarthritis) (*n* = 33):** dry cupping	Baseline, at day 1, day 2, day 3, day 4	Drop outs (*n* = 8) [2-Ecchymosis, 3-registered no response, 3-missed the cupping session as per the study protocol]
	Group B (lumbar osteoarthritis) (*n* = 33): dry cupping		
	Group C (knee osteoarthritis) (*n* = 32): dry cupping		
Michalsen et al. [20] Germany	**Yoga group (*n* = 38):** Iyengar yoga	Baseline; at 4 weeks; at 10 weeks	Yoga group (*n* = 13) [1-didn't receive allocated intervention, 5- adverse events (1-related to intervention), 5-study non-compliance (bronchitis, sinusitis, migraine, low back pain), 2-other reasons (death of relative, change of workplace)]
	Exercise group (*n* = 39): Participants received standard self-care manual (developed by German Health Insurance Company) that specifically address exercise and education for chronic neck pain		Exercise group (*n* = 11) [1-adverse event (had surgery of hip joint earlier than expected, none related to intervention), 10-study non-compliance (wish to immediately start additional yoga or similar treatment)]

bias. Case reports and case series had a low risk of bias. Hence, there is a need for more high-quality original studies. In conclusion, the current systematic review documented considerably low frequency of adverse events following Ayush interventions for cervical or lumbar spondylosis. There is an urgent need to address, capture and reporting of adverse events in the Ayush studies for cervical and lumbar spondylosis through practitioners, researchers and health care system professionals.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40001-024-01985-3.

Supplementary Material 1: Table 1: PRISMA 2020 for Abstract checklist. Table 2: PRISMA 2020 checklist. Table 3: Inclusion and Exclusion criteria. Table 4: Diagnostic classification and codes for cervical and lumbar spondylosis in Allopathy and Ayush systems of medicine. Table 5: Database specific search terms and the number of articles retrieved. Figure 1: Description of selected articles based on Population, Intervention and study design. Figure 2: Publication of Ayush studies on Cervical and lumbar spondylosis during 1976-2021. Table 6: General Characteristics of selected studies. Table 7: Description of selected articles with comparison group. Table 8: Description of selected articles without comparison group. Table 9: Compliance of research mandates reported in selected articles. Table 10: Risk of bias assessment of selected articles. Table 11: Risk of bias assessment for Randomized Controlled Trials (RoB2). Table 12: Risk of bias assessment for Non- Randomized Controlled Trials (ROBINS-I tool). Table 13: Risk of bias assessment for Case reports (JBI tool). Table 14: Risk of bias assessment for Case series (JBI tool).

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Availability of data and materials
The datasets used and analysed during the present study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
Ethics committee review is exempted for conducting systematic reviews as per the guidelines of Indian Council of Medical Research—National ethical guidelines for biomedical and health research involving human participants, 2017.

Competing interests
The authors declare no competing interests.

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