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SLEEP BREATHING PHYSIOLOGY AND DISORDERS • REVIEW

Prevalence and assessment of sleep-disordered breathing in head and neck cancer patients: a systematic review

Guihua Hao[1,2] · Fen Gu[3] · Min Hu[1] · Wenjing Ding[4] · Wentao Shi[5] · Jingjing Dai[1] · Lili Hou[1]

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Abstract

Study objectives Sleep-disordered breathing (SDB) is a very common and underdiagnosed condition in head and neck cancers (HNC) patients. If untreated, SDB can lead to negative health consequences. The identification of SDB in HNC patients is crucial to ensure appropriate treatment and to improve outcomes. The purpose of the study was to investigate the incidence of coexisting SDB in HNC patients and to evaluate methods of assessing SDB in the population.

Methods A systematic search of PubMed, Embase, CINAHL, Cochrane Database, the Web of Science, and Scopus was performed for studies related to SDB in HNC patients. In total, 1713 articles were identified. 19 articles were selected for qualitative synthesis. The studies involved 584 subjects.

Results The prevalence of SDB ranged from 57 to 90% before cancer treatment and from 12 to 96% after. When using an apnea-hypopnea index (AHI) cut-off ≥ 5/h to diagnosis SDB, the prevalence of SDB was 57–90% before cancer treatment and 12–94% after treatment. Sleep studies using polysomnography are the most commonly used assessment tools, but thresholds for diagnosis have been inconsistent.

Conclusions There is a high prevalence of SDB in HNC patients. However, the diagnostic and thresholds methods used for detecting SDB vary widely. To determine the accurate prevalence of SDB, prospective, systematic studies of SDB in unselected cohorts of HNC participants are required.

Keywords Head and neck cancer · Sleep-disordered breathing · Prevalence · Sleep disturbance · Systematic review

Introduction

Head and neck cancer (HNC) is the sixth most common cancer in the world, affecting quality of life and increasing mortality rates [1]. The most common type of HNC is squamous cell carcinoma, and tumors can develop in structures close to the upper airway, causing anatomical abnormalities and predisposing patients to sleep-disordered breathing (SDB) [2, 3]. SDB with obstructive sleep apnea (OSA) as the predominant subtype, is increasingly recognized as a crucial modifiable risk factor for HNC [4]. A robust bi-directional association between SDB and HNC exists [5, 6], with evidence of negative synergy between the two conditions, and their co-occurrence has been associated with worse outcomes [7]. Conversely, evidence shows that treatment of SDB is associated with improved cancer outcomes. International cancer management guidelines have been developed to recommend the identification and treatment of coexisting SDB in cancer patients [8].

✉ Wentao Shi
shiwentaotobe@163.com

✉ Jingjing Dai
daijingjing8011@163.com

✉ Lili Hou
pisces_liz@163.com

1 Department of Nursing, Shanghai Ninth People's Hospital, School of Medicine, Shanghai jiaotong University, 639 S Zhizaoju Rd, Shanghai 200011, China

2 Shanghai JiaoTong University School of Nursing, No.227 South Chongqing Road, Shanghai, China

3 Department of Nursing, Huadong Hospital Affiliated to Fudan University, Shanghai, China

4 Shanghai Jiaotong University School of Medicine Library, Shanghai, China

5 Clinical research unit, Shanghai Ninth People's Hospital, School of Medicine, Shanghai jiaotong University, 639 S Zhizaoju Rd, Shanghai 200011, China

Despite the importance of SDB, accurate estimates of SDB prevalence in HNC patients are not available [9]. There exist several challenges in identifying comorbid SDB in HNC patients, including the lack of routine SDB symptoms in this population [10], barriers relating to medical access and cost-related obstacles, as well as insufficient understanding of the accurate prevalence of SDB in HNC population [7]. Surmounting these obstacles would help to assess the magnitude of the serious issue of SDB in comorbid HNC, leading to improved clinical awareness and optimal allocation of medical and research resources.

Thus, we performed a systematic review to: investigate prevalence of SDB among HNC patients, evaluate variation in SDB detection in existing studies. The results may provide new evidence to help manage HNC.

Materials and methods

Search methodology

This study was performed according to the Preferred Reporting Item for Systematic Reviews and Meta-Analyses (PRISMA) protocol [11] and guidelines [12]. An electronic systematic search was conducted, assisted by an experienced librarian, encompassing these databases: PubMed, Embase, CINAHL, Cochrane Database, the Web of Science, Scopus from inception to December 2022. Relevant text terms and Medical Subject Headings containing SDB and HNC terms were used to develop the search strategy for each database. The search was restricted to human trials in English. Detailed information of the research strategy was outlined in supplementary Appendix S1.

Study selection

Studies that investigated the prevalence and assessment of SDB in HNC patients were screened based on several criteria. Inclusion criteria: (1) experimental, observational or prospective cohort studies; (2) study participants with HNC and aged over 18 years (mean age); (3) reporting of the percentages of patients with SDB; (4) the method used to determine SDB according to standardized sleep study classifications [13]; (5) the diagnostic cutoffs for SDB had to be clearly defined; (6) absence of control of the HNC population prior to the SDB trial. Exclusion criteria were as follows: (1) Studies that focused solely on different aspect of sleep, like insomnia, restless leg syndrome, or naps; (2) studies that involved inappropriate study populations, such as pediatric patient; (3) duplicate researches; (4) Other type of paper (e.g., reviews, case reports, abstracts).

Studies were selected for inclusion according to the PRISMA flowchart [12]. An initial screening was conducted by a single reviewer (GH) using the titles and abstracts. A second reviewer (FG) independently reviewed the titles and abstracts of records that were potentially relevant. The identified studies were screened for full-text by the two reviewers (GH and FG) independently. The final decision on inclusion was made by the two reviewers after considering the criteria for inclusion and exclusion. The study selection flowchart is shown in Fig. 1, with any differences in the selection process being addressed and resolved by the senior author (LH).

Data extraction and outcomes

As part of the review process, data were extracted by two reviewers (GH and FG) independently. For each study, information was summarized using a matrix that included general information and the disease status of the participants. Several characteristics of SDB were distinguished, including SDB identification, SDB definition, timing of SDB diagnosis, and SDB treatment. If further information or clarification was necessary, we contacted the authors of the chosen studies.

Quality assessment

Each article was independently assessed for study quality by two reviewers (GH and FG). Any discrepancies that arose were resolved through discussion or arbitration by senior author (LH). The quality of the included studies was assessed using the Newcastle-Ottawa Scale (NOS) [14] and the modified NOS [15]. The NOS is an assessment of the quality of cohort studies from three aspects: Selection, Comparability, and Outcomes. The modified NOS [15] was used to assess the quality of cross-sectional studies in the same three aspects.

Results

Study selection

1713 records were identified, out of which 781 studies were screened by title and abstract. 122 full-studies were retrieved, 103 were excluded for reasons outlined (Fig. 1). Finally, 19 studies were incorporated into ultimate analysis.

Quality appraisal

Eight cohort studies ranged from five to seven stars according to the NOS, while the eleven cross-sectional studies

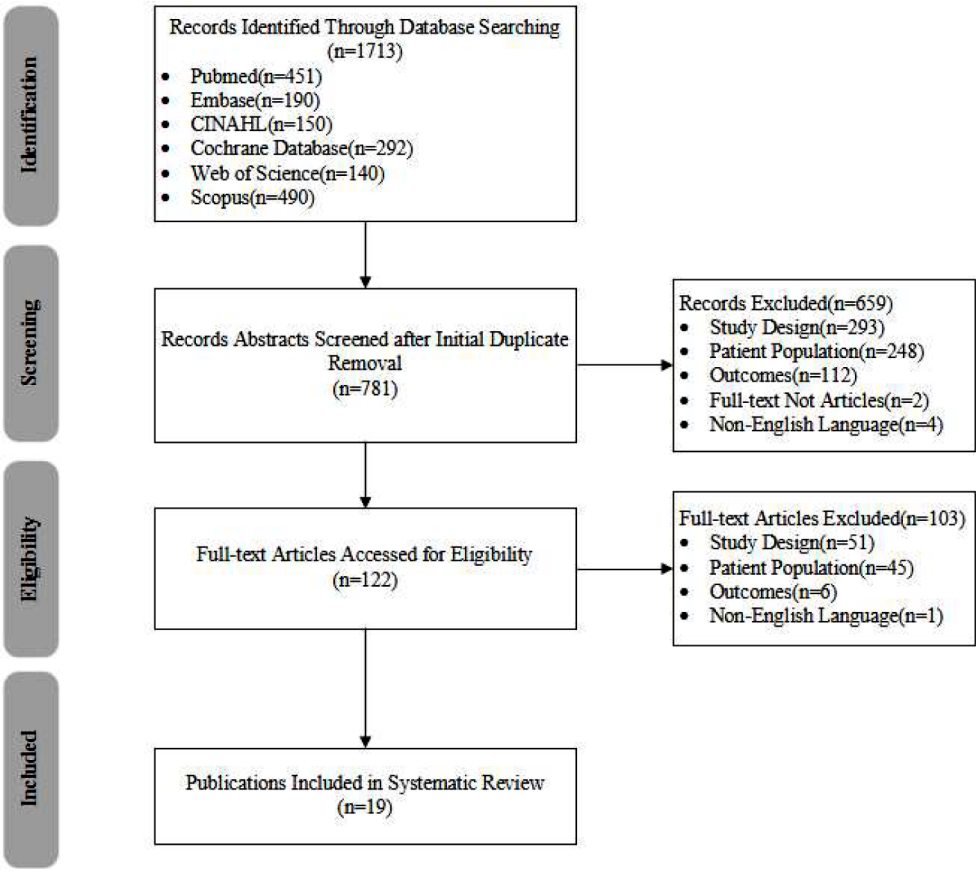

Fig. 1 Study selection flow chart

Table 1 Quality appraisal with the ottawa-newcastle scale ($n=19$)

Study, year	Design	Selection	Comparability	Exposure/ outcome
The Ottawa-Newcastle Scale				
Inoshita, 2022 [16]	PC	★★★	★★	★★
Huppertz, 2021 [17]	PC	★★★	★★	★
Saesen, 2021 [18]	PC	★★★	★	★
Loth, 2017 [19]	PC	★★★★	★★	★
Huang, 2021 [20]	PC	★★★	★	★★
Gilat, 2013 [21]	RC	★★	★	★★
Lin, 2014 [22]	PC	★★	★	★★
Ouyang, 2019 [23]	PC	★★★	★★	★★
The Modified Ottawa-Newcastle Scale				
Payne, 2005 [24]	CS	★★★	★★	★★
Nesse, 2006 [25]	CS	★★★	★★	★★
Faiz, 2014 [26]	CS	★★★	★	★★
Friedman, 2001 [27]	CS	★★★	★	★
Gavidia, 2022 [28]	CS	★★★	★★	★★
Israel, 2006 [29]	CS	★★★	★★	★★
Steffen, 2009 [30]	CS	★★★	★	★★
Qian, 2010 [31]	CS	★★★	★	★
Chan, 2012 [32]	CS	★★★	★★	★★
Teixeira, 2013 [33]	CS	★★★	★	★
Huyett, 2017 [34]	CS	★★	★★	★

Notes PC, prospective cohort; RC, retrospective cohort; C-S, cross-sectional

rated by the Modified NOS also ranged from five to seven stars. Most of these controlled for confounding factors and were therefore of high quality in the comparability category. Most of these studies had low bias in the exposure or outcome category (Table 1).

Study characteristics

Characteristics of the 19 selected articles that reported on the proportion of SDB in HNC patients and how SDB was determined are shown in Table 2. The studies were published between 2001 and 2022, with most of them conducted in the USA, Canada, and European countries. Most of these studies used cross-sectional designs ($n=11$), while the remaining eight used either prospective or retrospective cohort designs. A total of 584 HNC patients were included in these studies, most studies with sample sizes below 50 participants. The study sample varied from $n=14$ to $n=67$ participants. Approximately 30–96.9% of the subjects were male HNC patients. The most common tumor type was squamous cell carcinoma (SCC), of which all subjects in fifteen trials had SCC. In most studies, the location of tumors in HNC patients has tended to focus on specific areas such as the tongue, larynx, nasopharynx and oropharynx. Surgery

Table 2 Summary of studies and characteristics of patients with HNC tested for sleep-disordered breathing

	Study, Country/year	Study design	Dates	Sample size	Age, years mean ± SD or median(IQR)	Men, %	BMI, kg/m^2	Cancer type	Cancer site	Cancer treatment (%)
1	Payne et al., Canada/2005 [24]	CS	Not report	17	64(42–76)	58.8	27(16-37)	SCC	Oral, oropharynx	Surgery (76), other (24)
2	Inoshita et al., Japan/2022 [16]	PC	May 2017-August 2020	32	64.8 ± 11.8	96.9	22.7 ± 3.6	SCC, no SCC	Nasopharynx, Oropharynx, Hypopharynx, Larynx	RT (97), other (3)
3	Nesse et al., TheNetherlands/2006 [25]	CS	May 2004-October2004	33	62 (38–87)	69.7	25(16–35)	SCC	Tongue, oropharynx, oral floor, tonsil	Surgery (39), RT (22), combined (39)
4	Faiz et al., USA/2014 [26]	CS	2006–2011	56	60b (28–87)	76.8	29b (12–70)	SCC, no SCC	Oropharynx, larynx, oral, nasopharynx, nasal cavity, salivary gland	RT (79), surgery (21)
5	Huppertz et al., Germany/2021 [17]	PC	January 2018-June 2019	33	64.42 ± 7.83	81.8	Pre:24.83 ± 3.63, post:22.82 ± 3.76	SCC	tongue, oropharynx and hypopharynx	CRT (36), surgery (64)
6	Saesen et al., Belgium/2021[18]	PC	2016–2017	50	64.2 (32–88)	66		SCC	Hypopharynx, Larynx, Oropharynx	RT (18), CRT (20) Surgery with radiotherapy (50), Surgery with chemoradiotherapy (12)
7	Loth et al., France/2017 [19]	PC	January 2013 -February 2015	51	61.1 (44–76)	72.5	23 (16–33)	SCC	Hypopharynx	CRT (80), CRT + surgery (20)
8	Friedman et al., USA/2001 [27]	CS	Not report	24	64.8 (39–89)	87.5	22 (16–31)	SCC	Larynx, tongue, pharynx	Surgery (100), RT (42)
9	Huang et al., Taiwan/2021 [20]	PC	2017–2019	15	56.2 ± 12.8	93.3	NA	N/A	Tongue, buccal, tonsil	Surgery (100)
10	Gavidia et al., USA/2022 [28]	CS	July 2017-June 2018	67	62.0 ± 7.7	85	28.7 ± 4.6	SCC	Tongue	CRT (75), other (25)
11	Israel et al., Brazil/2006 [29]	CS	Not report	22	65.5 (50–80)	90.9	25 (19–31)	SCC	Larynx	Surgery (100)
12	Steffen et al., Germany/2009 [30]	CS	2006–2008	31	64.5b (48–77)	70.9	25b (18–35)	SCC	Oropharynx, larynx	Surgery (100), RT (66)
13	Qian et al., Canada/2010 [31]	CS	Not report	24	60.2 (54–64)	66.7	28 (15–47)	SCC	Oral	Surgery (13), CRT (7), combined (50)
14	Chan et al., Taiwan/2012 [32]	CS	January-April 2009.	26	52 (32–71)	92.3	25 (19–35)	SCC	Tongue	Surgery (100), CRT (65)
15	Gilat et al., Israel/2013 [21]	RC	2006–2010	15	57 ± 19	30	24.1 ± 4.3	N/A	Tongue	Surgery (100)
16	Teixeira et al., Brazil/2013 [33]	CS	2000–2008	14	64.9 (41–84)	92.8	26 (19–29)	N/A	Larynx	Surgery (100), RT [35]
17	Lin et al., Taiwan/2014[22]	PC	Not report	18	49	83.3	Pre: 24; post: 21	NPC	Nasopharynx	CRT (100)
18	Huyett et al., USA/2017 [34]	CS	Not report	16	61.6b (48–75)	81.3	30b (22–39)	SCC	Larynx, oropharynx	CRT (88), RT (12)
19	Ouyang et al., China/2019 [23]	PC	June 2015 - March 2017	40	(44–67)	92.5	Pre: 23.3; post: 23.6	SCC	Larynx	Surgery (100)

Notes PC, prospective cohort; RC, retrospective cohort; C-S, cross-sectional; BMI = body mass index; N/A = not available; RT = radiotherapy; CRT = chemoradiation; SCC = squamous cell carcinoma; NPC = nasopharyngeal carcinoma; [b]Median was used instead of the mean

Table 3 Summary of sleep measures and characteristics of sleep-disordered breathing in patients with head and neck cancer

	Study, Country/year	SDB prevalence, %	Consecutive screening	Sleep study device level[a]	Cutoff Index to diagnose SDB	Sleep and other Scales	Pre/Post cancer treatment	SDB Treatment
1	Payne et al., Canada/2005 [24]	76	Y	PSG-level 2	AHI ≥ 20	None	Pre	No
2	Inoshita et al., Japan/2022 [16]	pre:81.3%, post:85.7%	Y	PSG-level 1	AHI ≥ 5	ESS, PSQI	Pre and Post	NA
3	Nesse et al., TheNetherlands/2006 [25]	12	Y	PSG-level 2	AHI ≥ 5 + symptoms	ESS, OSA symptoms questionnaire	Post	No
4	Faiz et al., USA/2014 [26]	84	Y	PSG-level 1	AHI ≥ 5	ESS, PSQI	Post	PAP, 75% adherence
5	Huppertz et al., Germany/2021 [17]	pre:90, post:94	Y	PO-level 4	AHI ≥ 5	EORTC QLQ c30	Pre and Post	NA
6	Saesen et al., Belgium/2021 [18]	40	N	BQ	BQ ≥ 2	ESS, BQ	Post	NA
7	Loth et al., France/2017 [19]	25.5	Y	PSG-level 3	AHI ≥ 10	(1) ESS; (2) EORTC QLQ C-30; (3) EORTC H&N 35	Post	PAP, 36% adherence
8	Friedman et al., USA/2001 [27]	91.7	Y	RDI-level 1	RDI ≥ 15	10 Symptoms questions	Post	PAP, 36% adherence
9	Huang et al., Taiwan/2021 [20]	93	Y	PSG-level 1	AHI ≥ 5	None	Post	NA
10	Gavidia et al., USA/2022 [28]	60	N	SB	SB ≥ 3	None	Post	NA
11	Israel et al., Brazil/2006 [29]	86	Y	PSG-level 1	AHI ≥ 5	ESS	Post	NA
12	Steffen et al., Germany/2009 [30]	19	Y	RDI-level 3	RDI ≥ 20	ESS, clinic visit	Post	NA
13	Qian et al., Canada/2010 [31]	96	Y	RDI-level 1	RDI ≥ 15	ESS	Post	PAP, 0% adherence due to intolerance
14	Chan et al., Taiwan/2012 [32]	53.8	Y	PSG-level 1	AHI ≥ 5	None	Post	No
15	Gilat et al., Israel/2013 [21]	53	Y	PSG-level 1	AHI ≥ 5	ESS	Post	NA
16	Teixeira et al., Brazil/2013 [33]	92.8	Y	PSG-level 1	AHI ≥ 5	ESS	Post	No
17	Lin et al., Taiwan/2014 [22]	Pre: 72; post: 78	Y	PSG-level 1	AHI ≥ 5	ESS, SRBD symptoms, Snore VAS	Pre and Post	PAP, 0% adherence due to xerostomia
18	Huyett et al., USA/2017 [34]	50	Y	PG-level 3	AHI ≥ 5	ESS, FOSQ-10	Post	NA
19	Ouyang et al., China/2019 [23]	Pre: 57; post: 82	Y	PSGlevel 1	AHI ≥ 5	ESS	Pre and Post	No

Notes[a]Sleep study devices: level 1 is an attended in-laboratory baseline polysomnography; levels 2, 3, and 4 are home sleep apnea tests. AHI = Apnea Hypopnea Index; ESS = the Epworth Sleepiness Scale; EORTC H&N 35 = the European Organization for Research and Treatment of Cancer Head and Neck Cancer module; EORTC QLQC-30 = the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire; BQ = the Berlin Questionnaire; SB = the STOP-BANG questionnaire; FOSQ-10 = Functional Outcomes in Sleep Questionnaire; N/A = not available; PAP = positive airway pressure; PSQI = Pittsburgh Sleep Quality Index; PO: pulse oximetry; PG: polygraphy; RDI = respiratory disturbance index; RT = radiotherapy; Snore VAS = snoring visual analog scale; SRBD symptoms = sleep-related breathing-disorders symptoms

was the most common cancer treatment, followed by radiotherapy (RT) and chemoradiation (CRT).

SDB prevalence

The prevalence of SDB ranged from 57 to 90% before cancer treatment and from 12 to 96% afterward. When using an apnea-hypopnea index (AHI) cut-off ≥ 5/h to diagnosis SDB, 12 studies were included, prevalence of SDB ranged from 57% to 90% before cancer treatment and from 12 to 94% after treatment. However, only 4 studies assessed SDB before and after cancer treatment, and all of them reported an increase in the prevalence of SDB after treatment. The most common treatment for SDB was positive airway pressure (PAP), with five studies evaluating PAP therapy and reported adherence ranging from 0 to 75% (Table 3).

SDB ascertainment

The majority of studies ($n = 17$;89%) were used the level 1–4 test to determine SDB presence in a total of 467 participants (79.9%). Pulse oximetry was used in 1 study (5%) involving 33 patients (5.7%). Polygraph was also used in 1 study (5%) that included 16 patients (2.7%). 3 studies (16%) relied on the respiratory disturbance index (RDI) and included 79 patients (13.5%), while 2 studies (10.5%) used questionnaire-based tools (BQ or SB) and included 117 patients (20%) (Table 3).

SDB diagnostic thresholds

The most common threshold used to diagnose SDB was an AHI ≥ 5 /h ($n = 12$;86%). AHI ≥ 10 /h was used as a cut-off in one study, while another one used AHI ≥ 20 /h (5%). The prevalence reported in these studies ranged from 12 to 94%. Only 1 study combined symptoms of SDB with AHI to diagnose SDB.

Three studies used an RDI with thresholds of ≥ 15 or 20 events/h to diagnose SDB (20 events/h in 1 study, 15 events/h in 2). Only 2 studies used the questionnaire-based assessment, with diagnostic criteria of a BQ ≥ 2 and a SB score of ≥ 3.

Discussion

Our main finding is the high prevalence of SDB among HNC patients. In addition, most of the studies utilized polysomnography to identify SDB. However, the diagnostic threshold varied and a small proportion of studies used questionnaires to assess presence of SDB.

SDB is largely prevalent and underdiagnosed in HNC patients [24]. The most prevalent form of SDB is obstructive sleep apnea (OSA). There has been increasing research into how SDB and HNC relate to each other, with several plausible explanations for these associations. Prior to therapy, SDB in HNC patients may be due to structural abnormalities caused by the growth of masses that obstruct the airway. After treatment, surgery and/or radiotherapy can also lead to structural changes that contribute to SDB. For instance, thickening of the arytenoid mucosa, loss of support following the complete or partial removal of the thyroid cartilage [35], and displacement of the tongue can all lead to a reduction in the posterior airway space, as observed in those treated with supracricoid partial laryngectomy versus vertical partial laryngectomy [23]. Another possible explanation for comorbidity is anatomical nerve damage from lymph node metastases and/or the primary tumor itself, or radiotherapy and/or chemotherapy induced neuropathies [7]. Additionally, some researchers have proposed that edema occurs after radiation in HNC patients may be a risk factor for SDB [23]. In addition, we found that the prevalence of SDB was slightly lower after cancer treatment than before, but it is unclear whether the surgery to remove the tumor was the cause. While the link between SDB and NHC can be reasonably explained, it is still uncertain whether SDB actually causes or exacerbates the development of this type of cancer. To clarify this matter, a more comprehensive understanding of the molecular processes is necessary, and the future research should focus on identifying the specific mechanisms and signaling pathways that connect SDB and HNC.

Having a heightened clinical awareness is crucial when dealing with SDB in HNC patients, as the presentation is not always typical. Other potential causes of the patient's symptoms may be masked by the systemic manifestations of the malignancy or its treatment. Therefore, it is important to be proactive in detecting SDB in these patients, which may reduce the overall burden of their symptoms. International guidelines for managing HNC recommend assessing and treating SDB to improve patient outcomes and quality of life [36, 37]. However, detecting SDB is a challenge. Polysomnography measurement is a time-consuming and resource-intensive procedure with limited availability, especially in medical facilities [38]. In order to increase availability, simpler tests, such as home sleep apnea tests, have been developed and validated. However, this comes at the cost of some loss of accuracy, which must be balanced against efficiency and patient care [39]. This may explain the variation seen in the prevalence of SDB between studies, which use a variety of tests and diagnostic cut-offs. Although the accuracy of home sleep testing as a substitute for PSG has been questioned [40], a recent meta-analysis found that wearable sleep study devices that provide accurate sleep measurements are strongly associated with PSG results [41]. Therefore, wearable sleep devices may be a useful adjuncts or screening tool in the diagnosis of SDB. In our study, the main indicator used to diagnose SDB is the AHI, which counts apnea and hypoventilation events, however, it does not reflect many of the characteristics that are associated with SDB [42]. In addition, the exact definition, scoring method, and reproducibility of detecting hypopnea varies widely, raising further problems for the AHI as a diagnostic measure [43].

Importantly, the significant variation in the evaluation of SDB found in the qualitative analysis complicates the interpretation of the role of SDB in HNC from existing studies, as the comparability of these researches may be limited. Although questionnaires can be a useful tool for the assessment of SDB in certain populations, the American Academy of Sleep Medicine advises against using questionnaires to

diagnose SDB without polysomnography or a home sleep apnea test because of the potential for error [13]. We found that two studies used only questionnaire instruments (mainly BQ and SB) to assess SDB, calling into question the validity of these results and hindering further understanding of the association of SDB with HNC. Although it cannot be used to diagnose SDB, the use of a sleep questionnaire can help identify patients at risk. The ESS is a short, eight-question validated and reliable tool for assessing daytime sleepiness and is commonly used to screen patients for possible SDB [44]. We found that the majority of included studies used the ESS as an adjunct assessment tool.

From both a clinical and research perspective, assessment of the prevalence of SDB and HNC is the first step in their management. This study highlights the large range of previously reported prevalence of SDB, from 12 to 96%, which reflects the enormous heterogeneity in the method of assessment, the diagnostic definitions used and the populations studied. Future investigations require large-scale prospective studies to better understand the accurate prevalence of SDB in HNC. Perhaps a longitudinal approach could be used to provide more accurate recommendations for assessing and managing SDB among HNC patients.

The present study has several limitations. First, most studies were cross-sectional, which reduces their strength of evidence. Second, the study included a small sample size, and the methodological quality of most studies was insufficient, with inadequate information provided on participant, and non-validated tools used to measure sleep. The results of this study should be interpreted cautiously. Finally, our study focused only on SDB diagnosed on the basis of AHI thresholds. However, we did not analyze incidence of central or obstructive sleep apnoea, hypoxaemia, or sleep quality. These factors are crucial in the development and prognosis of HNC [45, 46].

Conclusion

In summary, there is a high prevalence of SDB in HNC patients. The diagnostic tools currently used to diagnose SDB in HNC patients are mostly PSG or home sleep test with relatively uniform diagnostic thresholds. Larger studies will be necessary in the future for confirmation of the prevalence of SDB in HNC patients. Ideally, these studies should use both validated questionnaires and objective methods to diagnose SDB. The findings may be a scientific basis and research direction for the assessment of SDB for the improvement of outcomes in HNC patients.

Author contributions Guihua Hao, Jingjing Dai and Lili Hou designed the study; Guihua Hao and Wenjing Ding conducted the database search, study selection and data extraction process; Guihua Hao and Fen Gu conducted quality assessment of screened studies; Guihua Hao and Wentao Shi participated in the statistical analysis. Guihua Hao, Min Hu and Lili Hou drafted the manuscript and have primary responsibility forfinal content. All authors have read and approved the final version of the manuscript and agreed to submit it for publication.

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Data availability The authors confirm that the data supporting the findings of this study are available within the article and/or its supplementary materials.

Declarations

Ethical approval For this type of study formal consent is not required.

Informed consent This article does not contain any studies with human participants performed by any of the authors.

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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