Primary vs. Specialist Care in Management of Sleep Apnea

Commentary on Chai-Coetzer CL, Antic NA, Rowland LS, et al. Primary care vs. specialist sleep center management of obstructive sleep apnea and daytime sleepiness and quality of life: a randomized trial. *JAMA* 2013;309:997-1004.

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Summary of Primary Care vs. Specialist Sleep Center Management of Obstructive Sleep Apnea and Daytime Sleepiness and Quality of Life: A Randomized Trial

Question: Is a primary care led, ambulatory, simplified approach to diagnosis and treatment of obstructive sleep apnea (OSA) similar in clinical efficacy to specialist sleep center care?

Design: Randomized, controlled, non-inferiority trial; anzctr.org.au Identifier: ACTRN12608000514303.

Allocation: Randomization was conducted by a telephone call to a clinical trials pharmacist independent of the study, using a computer-generated random numbers list.

Blinding: The investigators and participants were not blinded to study arm assignment.

Follow-Up Period: 6 months.

Setting: Participants were recruited from 4 geographical locations in South Australia (metropolitan and rural primary care and nurse led community practices, and a university hospital sleep center in a metropolitan region).

Subjects: 155 adults, mean age 57.2 (n = 81, Primary care) and 54.5 (n = 74, Specialist sleep center), 69% and 57% male, respectively, were randomized. **Inclusion Criteria:** a high diagnostic likelihood of moderate to severe OSA defined as a score of ≥ 5 on a screening questionnaire and an overnight 3% oxygen desaturation index (3%ODI) of ≥ 16 events per hour, and an Epworth Sleepiness Scale (ESS) score ≥ 8 or persistent hypertension despite taking 2 or more antihypertensive agents. **Exclusion Criteria:** 1) Body mass index (BMI) > 50 ; 2) neuromuscular disease; 3) unstable psychiatric disease or cognitive impairment considered likely to interfere with adherence to instructions, completing the study or managing CPAP; 4) hospitalization in the previous 3 months for myocardial infarction, unstable angina, cardiac failure, or cerebrovascular accident or New York Heart Association class III or IV symptoms; or 5) lung disease with awake resting oxygen saturation of less than 92%.

Intervention: Patients meeting eligibility criteria were randomized into either primary care management or standard care offered at a specialist sleep center. Both plans included treatment of OSA with continuous positive airway pressure, mandibular advancement splints, or conservative measures only. The primary care physician and community nurse participated in a 6 hour educational program on OSA and its management prior to treating patients. Additionally, the community nurse received 5 days of in-service training with specialist nurses at the

tertiary sleep center. Home Auto-titrating CPAP was used over 3 consecutive nights to determine a fixed treatment pressure based on the 90th or 95th (S8 AutoSet Spirit) percentile pressure. CPAP devices were converted to a fixed pressure mode for the remainder of the study.

In the sleep specialist arm, in lab baseline, CPAP titration, or split night polysomnography decisions were left to the discretion of the treating physician. Follow-up phone and clinic visit contact was identical in both arms.

Outcomes: The primary outcome was the change in ESS score from baseline to 6 months. Secondary outcome measures were 6 month changes in the Functional Outcomes of Sleep Questionnaire (FOSQ), Sleep Apnea Symptoms Questionnaire (SASQ), Short-Form 36 Health Survey (SF-36) vitality and mental health components, CPAP adherence, blood pressure, and weight. Within trial sleep diagnostic and treatment costs were collected and compared during the 6-month follow-up.

The sample size was calculated to show the non-inferiority of the primary care arm relative to the specialist group in the mean change in ESS scores after 6 months using an a priori determined non-inferiority margin of -2.0 (based on past studies of minimal clinically important differences for health related quality of life instruments, clinical studies of variations in ESS scores and ESS responses to placebo CPAP in patients with OSA), assuming 90% power, a one sided type I error of 5%, and a standard deviation of 4.0 for the change in ESS score.

Patient Follow-Up: Intention to treat analysis with replacement of missing values by multiple imputations; 17 of 81 withdrew from primary care arm (79% completed follow-up), 6 of 74 withdrew from specialist arm (92% completed follow-up).

Main Results: There was no statistically significant difference between the groups in the primary outcome. Both management arms showed improvement in ESS after 6 months of therapy. In the primary care group, the mean baseline score of 12.8 decreased to 7.0 at 6 months ($p < 0.001$), and in the specialist group, the score decreased from a mean of 12.5 to 7.0 ($p < 0.001$). Primary care management was non-inferior to specialist management with a mean change in ESS score of 5.8 vs. 5.4 (adjusted $p = 0.43$). There were no differences in secondary outcome measures between groups. Total average costs per patient were estimated at US \$1,819.44 in the primary care group and US \$3,067.86 in the specialist group.

Conclusion: In adults with at least mild symptoms of daytime

sleepiness, moderate to severe oxygen desaturation index, and no significant pulmonary, cardiac or cognitive co-morbidities, a simplified management strategy for OSA based in primary care was not clinically inferior to specialist sleep center care in improving symptoms of daytime sleepiness.

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COMMENTARY

Various estimates of the prevalence of obstructive sleep apnea (OSA) in the U.S. are available and they range from as low as 2% to as high as 28% of the adult population. Examining specific patient populations such as those with hypertension, obesity, diabetes, stroke or ischemic heart disease would show much higher prevalences. So there is no doubt that primary care physicians seeing adult patients are managing a high percentage of patients with obstructive sleep apnea, and most of them are undiagnosed. I believe every sleep specialist in the U.S. would be ecstatic if the primary care physicians in their area routinely screened for OSA; but they don't.

One could speculate why they don't – too busy, too much hassle, the impression that patients won't wear CPAP, that it isn't an important diagnosis to make, the testing is too cumbersome, etc. But no matter what the reason, most patients in primary care clinics are not being routinely evaluated for OSA.

In the presented study, the authors show that teaching primary care physicians and their nurses about OSA can result in “non-inferior” outcomes compared to sleep specialists with the primary measure outcome being an Epworth Sleepiness Scale score (ESS). I applaud their efforts to show that such an endeavor can be successful; however, there are a few problems with the study and with translating its results to a U.S. model (the study was performed in Australia).

The study was a “noninferiority” study. It is much easier to show that a treatment is “not worse” than it is to show a treatment is better or even equivalent. A noninferiority study only has to show that a minimal level of effectiveness is present. The authors chose a 2 point improvement in ESS as their primary outcome. Is this the right outcome? ESS scores have been shown to vary quite a bit from day-to-day but it is frequently used scale that has validity (and was developed in Australia). We check ESS scores regularly in our clinic and while it is interesting information, it doesn't usually help much in management and a multidimensional evaluation such as the FOSQ, may have been a more appropriate primary outcome measure to assess true improvement. The secondary outcomes were also considered “noninferior” although a margin for each of these was not set. It should be kept in mind that such a study does not show that this approach is equivalent, just that it is not significantly worse than the “standard” treatment.

Another aspect of the study was that the sleep specialists were more likely to use different treatments compared to the patients cared for by the primary care team; 1/3 of the special-

ist's patients received an alternative therapy. This is probably because the sleep specialists are specifically trained to manage OSA and not just blindly apply CPAP to every patient. They would have the expertise to know which patients may be better candidates for CPAP, dental appliances or conservative treatments – isn't this why we have specialization in medicine? Additionally, the patients who saw sleep specialists were less likely to stop using CPAP – perhaps because they were better at educating them or choosing them – and, less likely to withdraw from the study. These important distinctions are buried in the details and not noted in the “headlines” of such a paper.

All those issues aside, what would be barriers to doing this in the U.S., outside of a research setting? First, you would have to start by convincing primary care doctors that this was important. Getting them to attend a 5 hour class about sleep apnea in between seeing patients, running an office, taking calls, documentation, etc, etc. We know that most don't ask about sleep symptoms and have not had adequate education in medical school or during CME sessions on sleep/wake disorders. If you could convince them to attend a class, then you would need to get them to rearrange their office practice so it could screen patients systematically, perform or at a minimum, order home sleep tests (HST), work with the myriad of DME providers who provide CPAP (as often third party payers have preferred providers), teach their office staff to do CPAP prescriptions and downloads. The home sleep testing and CPAP will require insurance approvals and follow-up visits. Additionally the physician will need to review the HST report, discuss options with the patient, order the auto PAP – which then has to be delivered, used and that data downloaded. The primary care provider needs to get the data and give an order to switch the machine to fixed PAP. And then the follow-up visit with someone – nurse or physician – to troubleshoot problems and document usage. Sure, this could be done, but given the constraints on most primary care practices in the U.S., I am not sure this will be seen as a high enough priority.

The model in the paper uses nurses to perform many of these tasks, which is fine, but where does the income come from? The nurse will not get paid for visits (or only at a low level), the staff will not get paid for the home sleep test (unless they do them themselves which sets up another whole level of complexity) nor for CPAP's, and the doctor visits are usually not reimbursed enough to take care of the overhead. Sleep Centers are much better equipped to perform these tasks and are the experts in diagnosis and treatment. Can it be done in primary care offices? Yes. The likelihood of this happening in most U.S. primary care offices – nil (in my humble opinion).

In conclusion, I wholeheartedly agree that primary care physicians should take a more active role in diagnosing, and even managing OSA. However, until education about sleep disorders is taught in medical schools and residencies and primary care physicians are knowledgeable about the diagnosis and management of OSA, the care of OSA should stay with the sleep specialist.

Response from Chai-Coetzer CL, Antic N and McEvoy D to Commentary by Collop N.

The science of the study was extensively canvassed during journal review and we do not think it particularly helpful to re-

visit Dr. Collop's criticisms concerning the statistical approach used, change in ESS as the primary endpoint etc. However, we do think it important to comment on the broader translational issues that she has raised. Dr. Collop wholeheartedly agrees that "primary care physicians should take a more active role in diagnosing, and even managing OSA" but then lists a series of perceived barriers. These include that PCPs and their nurses are already too busy and OSA diagnosis and management is too complex for them to be concerned with sleep apnea, that they lack the necessary education and that reimbursement models are not aligned with primary care management. She argues for maintenance of the status quo whereby sleep medicine specialists remain the sole providers of OSA diagnosis and management.

We believe the high prevalence of OSA in the developed and the developing world means we must change our approach to the diagnosis and management of OSA. Decades ago endocrinologists and internists provided the evidence, protocols and training for PCPs and specialist nurses to become actively involved with them in the management of diabetes, a disorder of comparable prevalence to OSA. Sleep medicine specialists are at similar point in history and in our view need to embrace and lead similar changes. Undoubtedly there are challenges ahead in evolving both the skills and knowledge of PCPs and nurse specialists in sleep medicine (incidentally, this applies to Australia as much as it does in the US) but if we dismiss this as all too hard we may miss a generational opportunity. Surely the way forward is to embrace the need for change and to lead the policy discussions and the education programs that build the necessary skills and knowledge, be this in medical and nursing schools, residency programs or amongst primary care physicians and nurses. New funding streams will obviously need to be developed to support these new models of care using evidence from our study, and others, that simplified diagnostic and management approaches to the care of OSA sufferers can provide care more cheaply without jeopardizing patient outcomes.

If we believe OSA is an important disease we must change our ways. Change can be difficult and at times confronting but as the evidence linking OSA with adverse health outcomes mounts we have a responsibility to our patients to make evidenced based diagnosis and management of OSA accessible to as many patients as we possibly can. Furthermore if the Sleep Medicine field does not lead the evolution of new models of care other groups will inevitably do so.

Response to Chai-Coetzer et al., from Collop N.

Contrary to what is written in this response, I did not "argue for maintenance of the status quo." Nowhere did I state that the current environment is ideal – what I did state in my last paragraph is that I "wholeheartedly agree that primary care physicians should take a more active role in diagnosing, and even managing OSA." On a personal note, I have been very proactive regarding education about OSA by speaking at our local primary care offices, on a national and regional level at internist and family practice physician's meetings and in medical schools and internal medicine residencies core lectures series. As AASM president, I organized a taskforce in the AASM to examine inclusion of PA and APN's in sleep centers; I have developed electives for internal medicine residents in sleep centers; we are in the process of setting up an online educational program for our nursing school to introduce sleep topics. No, I also disagree with the "status quo" and have spent a career teaching various groups about sleep and sleep disorders. But this is not going to happen overnight and the efforts must be aimed at further education of medical students, nursing students, advanced practice providers and in primary care residency programs. Sleep medicine specialists should be leading the way in this effort to educate these groups – which will lead to more patients with OSA getting appropriately diagnosed and treated. Interdisciplinary models of care are the way of the future and sleep centers will also need to figure out how best to facilitate the critical interface with primary care providers to provide the best outcomes for patients with sleep apnea.

CITATION

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DISCLOSURE STATEMENT

Drs. Collop and Shafazand have indicated no financial conflicts of interest.