●原 著

# 吸着式酸素濃縮器に組み込まれた加湿水が不要な加湿器の臨床的評価

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**要旨：在宅酸素療法に吸着式酸素濃縮器が主に使用されている．吸着式酸素濃縮器は水蒸気も除去するため産生された酸素ガスは乾燥している．近年，加湿水が不要な加湿器（膜式加湿器）が開発され酸素濃縮器に組み込まれている．しかし，加湿性能や有用性に関して報告がほとんどない．臨床的有用性を明確にするため，室内気の相対湿度と膜式加湿器を組み込んだ酸素濃縮器からの酸素ガスの相対湿度を測定し相関関係を調べた．また，慢性呼吸不全患者の鼻腔の主観的乾燥感も聴取した．室内気の相対湿度と膜式加湿器を組み込んだ吸着式酸素濃縮器からの酸素ガスの相対湿度は有意の正相関を認めた．加湿性能は室内気の水蒸気量に影響を受けるが，使用により鼻腔の主観的乾燥感が改善した患者を確認できた．新しい加湿器は加湿水を利用しないため呼吸器感染の潜在的危険因子を除去でき，加湿水の交換が不要で自動加湿できるため在宅患者の QOL 改善に有用と思われた．**

**キーワード：汚染，加湿器，膜式加湿器，酸素濃縮器**

Contamination，Humidifier，Membrane humidifier，Oxygen concentrator

## 緒 言

酸素吸入は肺胞におけるガス交換が障害され，低酸素血症状態にある患者の臨床病態改善に必要な治療手段である．慢性呼吸不全患者の長期管理に，持続的酸素吸入療法が有効であることは以前からよく知られている[1)]．携帯用酸素機器が1960年代に開発され，在宅酸素療法の基礎が築かれた．在宅酸素療法は，酸素療法が必要な慢性呼吸不全患者に対して住み慣れた自宅で療養を行える利点があり，患者の生活の質（QOL）を改善できる治療法である．在宅酸素療法に用いられる酸素供給装置は設置型酸素濃縮器，液化酸素および携帯用酸素ボンベなどがある．在宅で酸素を供給できる小型酸素濃縮器の開発で在宅酸素療法が簡便となり，本邦でも1985年に社会保険の適用が認められ広く普及している．

病院配管あるいは酸素ボンベからの酸素は相対湿度が0％近くまで乾燥している．さらに，広く使用されている吸着式酸素濃縮器は窒素を吸着する際に，水蒸気も除去するため，得られる酸素ガスは乾燥している．一般的に鼻腔，口腔などの気道粘膜，線毛運動の傷害を防ぐため，乾燥した酸素ガスは加湿器を用いて加湿される．臨床で用いられる加湿器は，乾燥した酸素ガスを加湿瓶に入った滅菌蒸留水の中をくぐらせ加湿する bubbling humidifier，滅菌蒸留水の入った加湿瓶の中をくぐらせず，上部を通過させるだけの pass-over humidifier などがある．加湿水を用いた再使用型の酸素ガス加湿器は院内肺炎，呼吸器感染症の潜在的因子になりうるため[2)~5)]，室内の湿度が十分に保たれていれば鼻カニュラの場合，日本呼吸器学会/日本呼吸管理学会ガイドライン[6)]では鼻カニュラで3L/分以下まで，米国呼吸療法協会（AARC：American Association for Respiratory Care）の酸素療法ガイドライン[7)]では鼻カニュラで4L/分以下まで，米国胸部学会（ATS：American Thoracic Society）ガイドライン[8)]では鼻カニュラで5L/分以下までの酸素流量ならば，あえて酸素を加湿しなくて良いとされる[6)~10)]．

本邦で世界に先駆け，酸素分子，窒素分子は拡散させず水分子を極めて容易に拡散・通過させる特殊膜を用いた加湿器が開発され，吸着式酸素濃縮器に組み込まれ臨床応用されている．加湿水の不要な加湿器（以下，膜式加湿器）は，以前我々が初めて開発した際，膜式加湿器と名付けている[11)~13)]．しかし，市販されている膜式加湿器が組み込まれた吸着式酸素濃縮器の加湿性能を臨床評価した報告はほとんどない．今回，本邦で商業的に利用可能な吸着式酸素濃縮器に組み込まれた膜式加湿器を臨床評価した．

## 対象と方法

空気は一定の水蒸気を含み，その空気中の水蒸気を厚みのある特殊な膜を用いて集め，内部を通過させた乾燥

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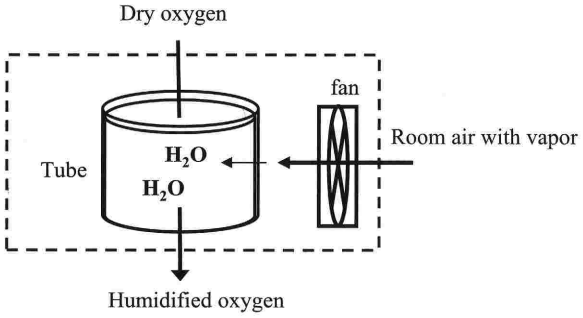


**Fig. 1** Structure and function of a membrane humidifier that does not need additional reservoir water. Air with water vapor is passed through an outer passage. Water vapor only permeates the tube with the membrane. Dry oxygen is passed inside the tube, and is humidified with water vapor.

酸素ガスに水分子を加えるという新しい技術が膜式加湿器の原理である（Fig. 1）．加湿性能と臨床的有用性を調べるため以下を検討した．本研究は鳥取大学医学部の倫理委員会の許可を得ている．

1．膜式加湿器が組み込まれた吸着式酸素濃縮器の加湿性能の客観的測定

膜式加湿器が組み込まれた吸着式酸素濃縮器，ハイサンソ 3C（帝人株式会社，東京）およびクリーンサンソ FH-22/5L（フクダ電子株式会社，東京）から産生された酸素ガスの相対湿度を測定し加湿性能を客観的に調査した．測定場所は鳥取県米子市，鳥取大学医学部附属病院で，測定時期は各季節が網羅できるようにハイサンソ 3C で 2006 年の冬期から 2007 年の冬期までの任意の延べ 50 日間，クリーンサンソ FH-22/5L は 2007 年の夏季から 2008 年の夏季までの任意の延べ 20 日間とした．各 1 台の機械を用いて測定した．

室内気の相対湿度と対象酸素濃縮器からの加湿酸素の相対湿度の関係を調べるためデジタル湿度計（TRH-CA，神栄株式会社，東京）を用いて（1）室内の相対湿度を測定，（2）従来型吸着式酸素濃縮器から加湿されていない酸素流の相対湿度を調べるため，膜式加湿器を組み込んでいない吸着式酸素濃縮器（FH-17/5L フクダ電子株式会社，TO-90-5L 帝人株式会社，各 1 台使用）から 20 分間，500ml の容器に加湿されていない酸素流を流しデジタル湿度計で容器内部の酸素ガス相対湿度を測定，(3) 膜式加湿器の性能を調べるため，膜式加湿器を組み込んである対象酸素濃縮器から 20 分間，500ml の容器に加湿された酸素流を流し容器内部の酸素ガス相対湿度を測定した．さらに，室内気の相対湿度と加湿された酸素流の相対湿度の相関関係を 2 社の機種で調べた．相対湿度測定時の吸着式酸素濃縮器からの酸素流量は 2L/分とした．相対湿度とは，その時の気温で大気中に含まれる水蒸気量を飽和水蒸気量で割り算し，百分率表示した値である．相対湿度は 0～100% までの値をとる．室内気の相対湿度と加湿された酸素流の相対湿度の直線相関は Pearson's coefficient を用いて，$p<0.05$ を有意とした（StatView, SAS Institute Inc., Cary, NC）．

2．慢性呼吸不全患者の酸素吸入時の主観的調査（鼻腔に対する乾燥感）

対象は酸素流量 3L/分以下の酸素吸入療法を受けている慢性呼吸不全の入院患者 17 人（慢性閉塞性肺疾患 9 人，間質性肺炎 2 人，肺結核後遺症 1 人，その他 5 人）．年齢は 76.9±6.8 歳，性別は男性 12 人，女性 5 人であった．全員，滅菌蒸留水を用いた加湿器を使用せず壁配管から酸素吸入を鼻カニュラで行っていた．これら対象患者に対して，鼻腔の乾燥感を感じているか聴取した．その後，膜式加湿器が組み込まれた吸着式酸素濃縮器を約 6 時間使用した後，主観的な鼻腔乾燥感を再度聴取した．患者には吸着式酸素濃縮器からの酸素ガスが加湿されていることを伏せて調査を行った．

## 結　果

1．室内気の相対湿度と膜式加湿器が組み込まれた吸着式酸素濃縮器からの酸素流の相対湿度の相関関係

膜式加湿器が組み込まれていない従来型吸着式酸素濃縮器からの加湿されていない酸素の相対湿度は室内気と相関はなく，2.7±1.5%（平均±標準偏差）であった．Fig. 2は室内気の相対湿度と帝人株式会社の膜式加湿器が組み込まれた酸素濃縮器（ハイサンソ 3C）からの加湿酸素相対湿度の相関関係である．Fig. 3は室内気の相対湿度とフクダ電子株式会社の膜式加湿器が組み込まれた酸素濃縮器（クリーンサンソ FH-22/5L）からの加湿酸素相対湿度の相関関係である．室内気の相対湿度と膜式加湿器が組み込まれた吸着式酸素濃縮器からの酸素流の相対湿度は各々正の相関を示した．相関式の傾きは Fig. 2で 0.8521, Fig. 3で 0.8524 とほぼ同一の値を示した．すなわち，酸素流量 2L/分では室内気の相対湿度の約 0.85 倍に酸素ガスを加湿可能となる．膜式加湿器の加湿能力は 2 機種で，ほぼ同等であるが，両者とも室内気の相対湿度に影響を受ける．

2．慢性呼吸不全患者に使用した際の主観的調査（鼻腔に対する乾燥感）

慢性呼吸不全患者に対して処方された壁配管の吸入酸素流量は 0.5L/分が 2 人，1L/分が 3 人，1.25L/分が 1 人，1.5L/分が 4 人，2L/分が 6 人，3L/分が 1 人であった．全例，加湿器を使用せず壁配管の酸素吸入を行っていた．壁配管の酸素を鼻カニュラで吸入して 17 人中 5 人（酸素流量，1.25L/分が 1 人，2L/分が 3 人，3L/分が 1 人）

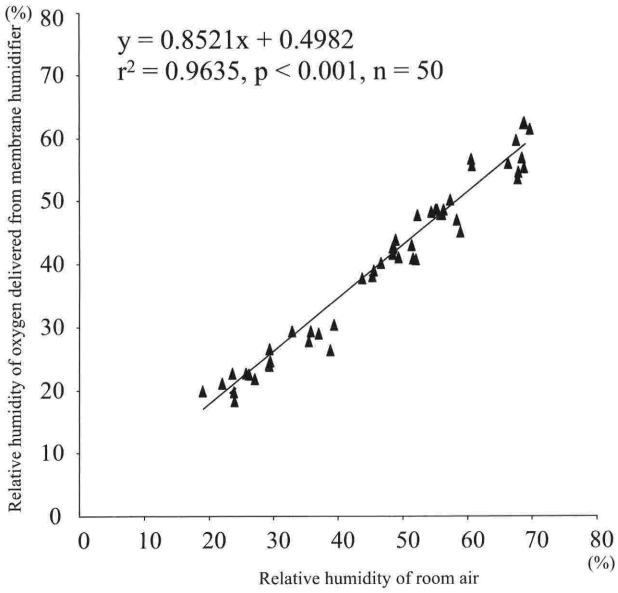


**Fig. 2** Single linear regression plot of relative room air humidity and of oxygen delivered by a PSA-type oxygen concentrator (HAI-SANSO 3C, Teijin Pharma Co, Tokyo, Japan) equipped with a membrane humidifier that does not need additional reservoir water.

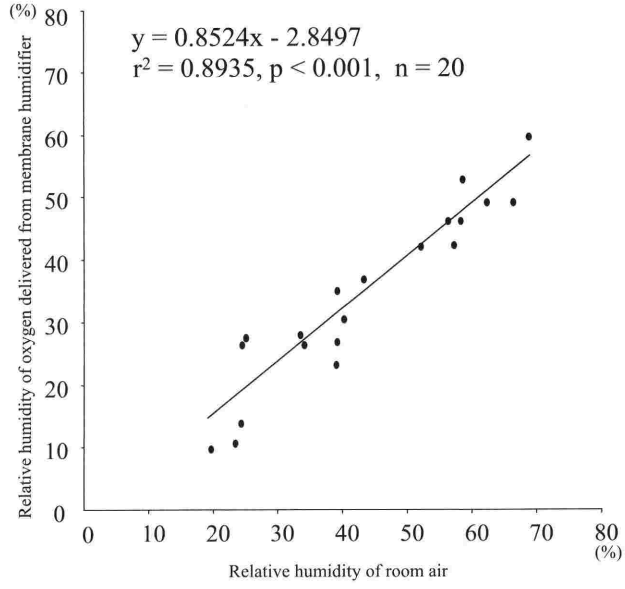


**Fig. 3** Single linear regression plot of relative room air humidity and of oxygen delivered by a PSA-type oxygen concentrator (Clean-SANSO FH-22/5L, Fukuda Denshi Co, Tokyo, Japan) equipped with a membrane humidifier that does not require additional reservoir water.

が慢性的に鼻腔の乾燥感を訴えていた．各酸素吸入流量を膜式加湿器が組み込まれた吸着式酸素濃縮器で約6時間使用，吸入した後，主観的な鼻腔乾燥感を聴取したところ，慢性的に鼻腔の乾燥感を訴えていた5人中3人が改善したと回答した（2L/分，3人）．

## 考　察

室内気の相対湿度と新型加湿器で加湿した酸素ガスの相対湿度の直線相関結果から，帝人株式会社とフクダ電子株式会社の酸素濃縮器に組み込まれている膜式加湿器の性能は，ほぼ同等と考えられた．また，長期酸素吸入している慢性呼吸不全患者において，3L/分以下の低流量酸素吸入でも鼻腔に乾燥感を自覚している患者がいることが分かった．鼻腔乾燥感を自覚する患者に対して膜式加湿器が組み込まれた酸素濃縮器を使用すれば乾燥感が改善する場合があることも明らかとなった．

酸素富化膜式酸素濃縮器と吸着式酸素濃縮器が設置型酸素濃縮器として利用されてきた．現在は使われていないが，酸素富化膜式酸素濃縮器は特殊な膜を利用する．酸素富化膜は気体分離膜の一種であり，窒素分子より酸素分子が容易に通過しやすい膜である．空気を酸素富化膜に出口側を減圧して通過させると膜に酸素分子が拡散して酸素濃度が約40%の酸素ガスを得ることができる．動作音が小さく，加湿器が不要（水分子は富化膜を通過するため）という利点があるが，得られる酸素濃度が低いため利用されなくなっている．現在主流の吸着式酸素濃縮器はpressure swing adsorption（PSA）式とも呼ばれる．吸着式酸素濃縮器は，圧力を加えると窒素を吸着する性質のゼオライトを用いて空気中の窒素を分離し酸素に富んだガスを得る装置である．得られる酸素濃度は約90～93%である[6]．ゼオライトは窒素だけでなく空気中の水蒸気も除去するため，得られた酸素ガスは乾燥している．以前は大型で動作音が大きかったが小型化改良も行われ，最も多く使用されている酸素濃縮器である[11)～13)]．

現在，広く普及している吸着式酸素濃縮器は，窒素吸着に使用するゼオライトが空気中の水蒸気も除去するため，患者が高流量の酸素吸入する際，加湿器で加湿する．従来，酸素濃縮装置に付随している加湿器は2種類ある．酸素ガスを加湿水に潜らせて加湿する“bubbling humidifier（気泡式）”と加湿水の上を通過させる“pass-over humidifier（表面気化式）”である．得られる相対湿度は酸素流量によって異なる[14]．前者は酸素流量3L/分までならば，酸素ガスを相対湿度で約60～90%程度に加湿できることが多いが[11)12)14)]，後者は相対湿度で約30～60%前後程度に加湿できると報告されている[14]．加湿水を使用した方法の欠点として，在宅で高齢者にとって滅菌蒸留水の交換が煩雑であり，継ぎ足しや交換忘れなどで細

菌，真菌による加湿水汚染の可能性がある．また，酸素ガスを加湿水に潜らせて加湿する“bubbling humidifier”は音が大きい．

最近になり，フクダ電子株式会社と帝人株式会社から“加湿水の不要な加湿器（膜式加湿器）”が開発され，吸着式酸素濃縮器に装備されている．加湿原理は，以前，我々が開発・報告した膜式加湿器と同じである[11)~13)]．空気は一定の水蒸気をもっており，その水蒸気を厚みのある特殊な膜を用いて集め，乾燥した酸素ガスに加えるという新しい技術である[15)]．我々の方法は，密閉されたシリンダー内に水分子のみを通過させるポリイミド系の膜を持った中空糸を約700本入れて，中空糸の外側に水蒸気を含んだ空気を加圧して通過させる．空気中の水分子は中空糸膜を拡散し，中空糸膜内部に入る．中空糸内部に吸着式酸素濃縮装置からの乾燥した酸素ガスを通過させると，中空糸膜外側から拡散した水によって加湿される．中空糸膜は細菌，真菌を通過させず，加湿水も使用しないため衛生的である[13)]．加湿用の水を交換する必要がないため簡便である．一方，加湿性能は空気中の水蒸気量に大きな影響を受ける[11)~13)]．

フクダ電子株式会社と帝人株式会社の市販されている吸着式酸素濃縮器に搭載されている膜式加湿器は，水分子のみを拡散させる中空膜を用いている点は同じであるが空気を積極的に加圧していないため，加湿性能は我々が開発した装置より低くなっていた．Fig. 2，3に示したように，室内気の相対湿度と加湿された酸素ガスの相対湿度は比例する．室内気の相対湿度と膜式加湿器が組み込まれた吸着式酸素濃縮器からの酸素流の相対湿度は各々正の相関を示し，相関式の傾きはFig. 2で0.8521，Fig. 3で0.8524とほぼ同一の値を示した．すなわち，両機種とも酸素流量2L/分の時は，室内気の相対湿度の約0.85倍に酸素ガスを加湿可能であった．しかし，酸素流量が増加すれば酸素ガスに対する加湿効果が低下すると予測され[14)16)]，その場合，Fig. 2，3の傾きは0.85より小さくなると推測される．一方，膜式加湿器が組み込まれていない吸着式酸素濃縮器からの酸素流の相対湿度は平均2.7%と乾燥しているため，在宅で24時間酸素吸入する患者にとって膜式加湿器が組み込まれた吸着式酸素濃縮器使用は利点があると考えられた．実際に入院中の患者に使用してみると，壁配管からの酸素吸入を加湿なしで行っていた患者で鼻腔乾燥感を自覚していた5人中，3人に自覚的改善を確認できた．Miyamotoらはvisual analog scaleで乾燥酸素吸入と加湿酸素吸入による鼻腔乾燥感を調べ，乾燥酸素流量が増すと健常者，呼吸器疾患患者ともに鼻腔乾燥感が強くなると報告している[17)]．また，吸着式酸素濃縮器に附属した加湿器に精製水を入れた群と入れない群で4週間使用後，自覚症状のアンケート調査をした研究で加湿器に精製水を入れて使用した群で有意に鼻の乾きが少なかったとする報告がある[18)]．

本研究の問題点として，膜式加湿器の性能を酸素流量2L/分のみの実験で測定した結果であり，壁配管からの酸素吸入と膜式加湿器が組み込まれた酸素濃縮器からの酸素吸入は実験者，被験者に対してブラインドでない点がある．今回，耳鼻科医師などによる客観的所見を調べていないため，今後visual analog scaleなどを含めて調べる必要もある．酸素の配管口にY字管をつなぎ片方に酸素加湿器（アクアパック®）を片方には直接，鼻カニュラを接続し患者に加湿の有無がわからないようにシングルブラインドで行った実験によると，鼻の乾燥感，喉や口の渇きの自覚症状は酸素ガス加湿によって有意な改善を認めなかったとする報告がある[19)]．しかし，この報告の中でも個々の患者をみると鼻の乾燥感，喉や口の渇きの症状が加湿により改善する症例があるため臨床的には自覚症状を訴える患者については柔軟に対応すべきとしている．さらに，膜式加湿器の問題点として室内気の相対湿度が低いと十分な加湿が得られない点がある．しかし，室内気の相対湿度が低いときに外側の水蒸気を含んだ空気を加圧する機能を追加すれば加湿性能を高められる可能性はある．

在宅酸素療法は慢性呼吸不全患者に対して重要な治療法である．本邦では酸素濃縮器を使って在宅酸素療法が容易に行える．新しい技術を付加価値として開発し，酸素濃縮器に組み込み在宅患者のQOLを改善させることは在宅酸素療法において新しい課題となっている．低流量酸素吸入時に酸素ガスを必ずしも加湿しなくてよいとされるが，乾燥感を訴える患者が存在するため新しい技術を応用した加湿水不要な膜式加湿器の在宅医療における意義は大きい．今後，膜式加湿器組み込みの臨床的効果に関して多数例で詳細な検討が有効性確認に必要と思われる．

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## Abstract

# Clinical evaluation of an oxygen concentrator and humidifier that does not require additional reservoir water

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A conventional humidifier with a reservoir of water for humidification can produce micro-aerosols contaminated with bacteria. The present study was undertaken to determine the clinical efficiency of a membrane humidifier that does not require additional reservoir water. We analyzed relative room air humidity and oxygen levels obtained from 2 pressure-swing adsorption (PSA)-type oxygen concentrators with membrane humidifiers. A significant correlation was found between relative room air humidity and that of oxygen moistened by a membrane humidifier. Several patients with chronic respiratory failure experienced improvements in subjectively reported nasal dryness using an oxygen concentrator with a membrane humidifier. This device avoids the need to change reservoir water, and may improve patient quality of life in the home.

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# Membrane Humidifier That Does Not Require Addition of Water

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**We developed a new device called "a membrane humidifier" which does not require an external water supply. Fifteen patients inhaled humidified-oxygen from the membrane humidifier and were asked about their subjective impression. The relative humidity of room air and that of humidified-oxygen from the membrane humidifier or a conventional bubble water humidifier were measured with a digital hygrometer. The relative humidity of the oxygen humidified by humidifiers was measured after the gas was flowed into a partially opened 500-mL container for 30 min. None of the patients experienced dryness of the nose or throat. All patients answered that there was no difference in their subjective impression between breathing oxygen from the membrane humidifier and from the conventional bubble water humidifier. A significant regression was observed between the relative humidity of room air and that of the oxygen humidified from the membrane humidifier. The membrane humidifier was able to produce humidification very well. This new compact device can be used not only in hospitals, but can also be incorporated in home oxygen concentrators. This new device also saves the procedure of changing water.**

**Key words:** humidifier; humidity; membrane humidifier

Bubble water humidifiers have conventionally been used to humidify dry gas (Hayes and Robinson, 1970; Mercke, 1975; Chalon, 1980). It is troublesome to clean the humidifier container and change the water. To reduce the risk of infection, the water reservoir must be cleaned periodically and the water must be changed frequently. We have developed a new device called "a membrane humidifier" whose function does not require the addition of external water for humidification. This new system obtains moisture from room air. It can be used not only in hospitals, but can also be incorporated in home oxygen concentrators (Burioka et al., 1997a,1997b). This technical study evaluated the membrane humidifier to determine its efficiency in humidifying dry oxygen.

## Subjects and Methods

### *Structure of the membrane humidifier*

The membrane humidifier is composed of a compressor and a steel cylinder containing several hundred hollow fibers made from polyimide resin (Fig. 1). The different permeation rate of gases is used to separate water molecules from the air (Mulder, 1996). Water vapor can permeate the polyimide membrane of a hollow fiber (UBE membrane, UBE Industries, Ltd., Tokyo, Japan) hundreds of times more readily than either nitrogen or oxygen (Nishimura, 1986). Compressed air with water vapor is passed outside the hollow fibers. As the room air is passed under high pressure through the space around the hollow fibers (outside passage), the water molecules in the air permeate the membrane of the hollow fibers. Dry oxygen from the hospital's oxygen supply is passed

through the hollow fibers (inside passage) within the membrane humidifier, and is humidified with water vapor (Fig. 2). One unit of hollow fibers is highly durable. The polyimide membrane of a hollow fiber can be sterilized with alcohol or disinfecting gases. The pressure of the compressed air was 196 kPa (2 kgf/cm$^2$) in this study although it was 98 kPa (1 kgf/cm$^2$) in our previous study (Burioka et al., 1997a, 1997b).

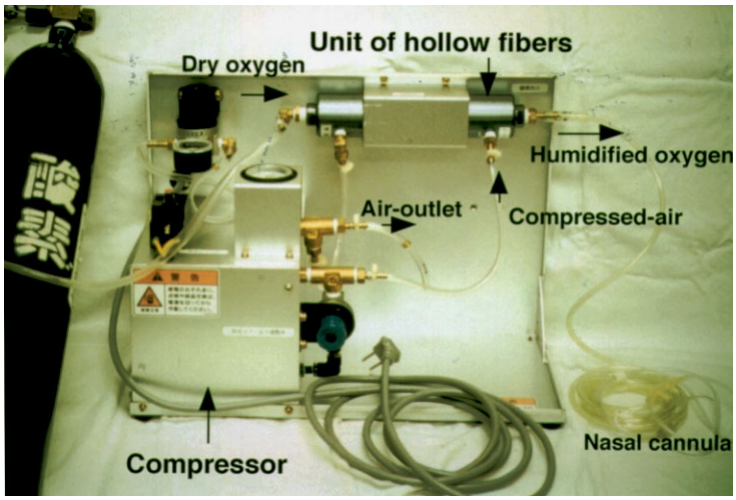


**Fig. 1.** Membrane humidifier. The membrane humidifier is composed of a compressor and a steel cylinder containing several hundred hollow fibers.

### *Patients*

We examined 15 patients (8 males and 7 females, mean age; 67.3 years old) who were hospitalized for chronic pulmonary disease (emphysema: 5 patients, interstitial pneumonia with collagen disease: 2 patients, sequelae of tuberculosis: 4 patients, idiopathic interstitial pneumonia: 2 patients, diffuse panbronchiolitis: 2 patients). Their clinical condition was stable. They were receiving oxygen therapy in the hospital. The study was explained and informed consent was obtained from patients before their participation.

### *Measurement*

After inhaling humidified-oxygen from both the membrane humidifier and conventional bubble water humidifier (Koike Medical Co., Tokyo) for 5 h, all patients were asked to fill out a questionnaire. We asked the patients whether their throat or nose was dried by the oxygen inhalation from the 2 humidifiers, and we also asked whether they felt some difference in their impression of inhalation between breathing oxygen from the new device and breathing oxygen from the conventional bubble water humidifier.

We measured the relative humidity of the room air, that of the dry oxygen from the hos-

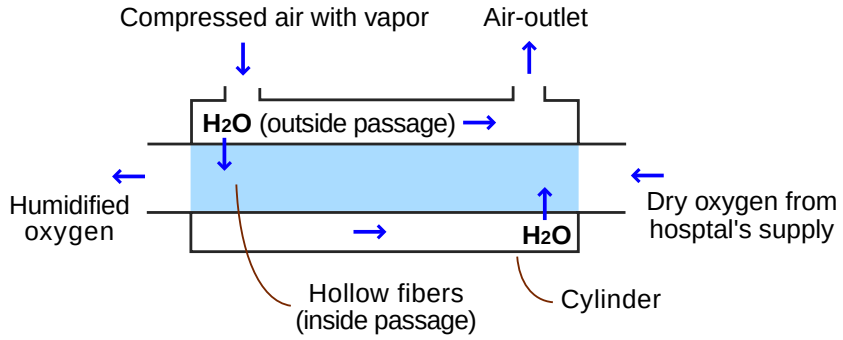


**Fig. 2.** Principle of humidification in one unit of hollow fibers. Compressed air with water vapor passes through the outside passage. Water vapor only permeates the hollow fibers. Dry oxygen from the hospital's supply passes inside the hollow fibers, and is humidified with water vapor.

pital's oxygen supply and that of the oxygen humidified by the membrane humidifier or the bubble water humidifier. The relative humidity was measured with a digital hygrometer (TRH-CA, Shin-ei Co., Tokyo, Japan), after the gases (1 L/min) had flowed into a partially opened container (500 mL) for 30 min. The pressure of the compressed air in the membrane humidifier was 196 kPa (2 kgf/cm$^2$). The temperatures in the laboratory room were maintained from 20 to 22°C during the study.

### *Data analysis*

Data are reported as mean ± SD. The significance of the results of multiple comparisons was calculated with a one-way analysis of variance by Turkey's test. Correlation between the relative humidity of room air and that of the oxygen flow humidified by the membrane humidifier was calculated using a regression curve with the software StatView-J 4.11 (Abacus Concepts Inc, Berkeley, CA). A level of $P < 0.05$ was considered statistically significant.

## Results

None of the patients experienced dryness of their nose or throat while breathing oxygen from the new device or the conventional bubble water humidifier. All subjects also answered that there was no difference in their subjective impression between while breathing oxygen from the new machine and while breathing oxygen from the conventional bubble water humidifier.

The relative humidity of the air in the laboratory room was 43.8 ± 14.9%. The relative humidity of the dry oxygen flow delivered by hospital's oxygen supply was 7.0 ± 1.0% after it had flowed into a partially opened 500-mL container for 30 min. A significant difference was observed between the relative humidity of the oxygen from the membrane humidifier (81.4 ± 8.2 %) and that from the conventional bubbling humidifier (88.9 ± 2.6%) ($P < 0.05$) (Fig. 3). A significant regression was observed between the relative humidity of the room air and that of the oxygen humidified by the membrane device (Fig. 4).

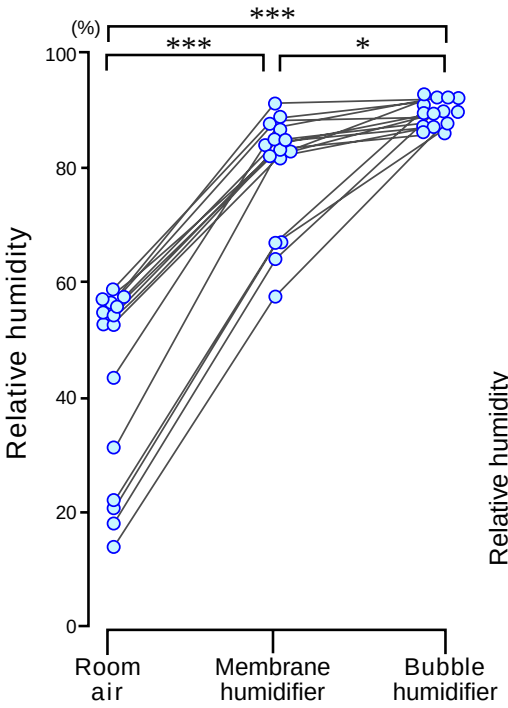


**Fig. 3.** Relative humidity of room air, oxygen humidified by the membrane humidifier, and oxygen humidified by the bubble water humidifier. ***$P < 0.001$, *$P < 0.05$ (Turkey's test).

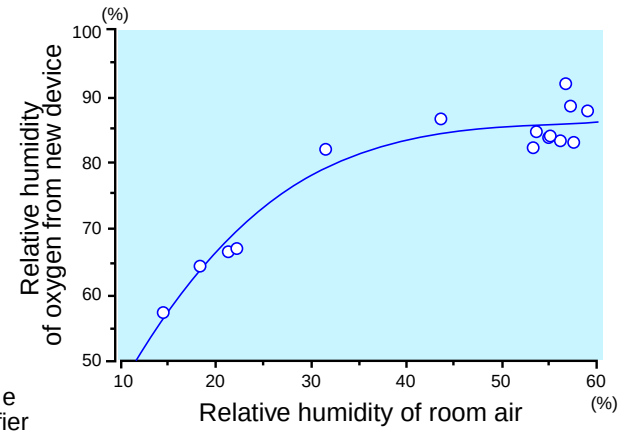


**Fig. 4.** There is a strong positive regression between the relative humidity of room air and that of the oxygen humidified by the membrane humidifier ($Y = 14.1X - 3.96X^2 + 0.0005X^3$ ($r^2 = 0.93$).

## Discussion

Dry oxygen is generally humidified by sterile distilled water when a supplement of oxygen is provided by nasal cannula in Japan. However, sterile distilled water is expensive, and it is troublesome to change the water in the reservoir. We developed a new humidifier that can humidify dry oxygen without the use of water.

A strong positive regression was observed between the relative humidity of room air and that of the oxygen humidified by the membrane humidifier. A significant difference was observed between the relative humidity of the oxygen humidified by the membrane humidifier and that humidified by the conventional bubble water humidifier (Fig. 3), because the relative humidity of the oxygen humidified by the new device was low when the relative humidity of room air was low (about 14–22%). Since this system obtains its water vapor from room air, it appears that its efficiency is diminished when the relative humidity of room air is low (Burioka et al., 1997a,1997b). However, even if the relative humidity of room air is about 14%, the membrane humidifier could humidify the dry oxygen to 55%. When the relative humidity of room was above 30 %, the relative humidity obtained from the membrane humidifier was almost the same as that of the conventional bubble water humidifier.

None of the patients experienced dryness of their nose or throat while breathing oxygen from the new device or the conventional bubble water humidifier. The membrane humidifier supplied well-moistured nasal oxygen without the need of water. This new device can be also incorporated in a PSA type oxygen concentrator (Burioka et al., 1997a,1997b) used in home oxygen therapy. The membrane humidifier will be beneficial in both hospitals and the home because it eliminates the laborious cleaning of the reservoir and changing of the water.

The polyimide membrane using hollow fibers has a dense layer pinhole-free surface. Its pore size is less than $10^{-3}$ μm (Nishimura, 1986; Mulder, 1996). Water vapor in the air dissolves and diffuses into a membrane wall. Since bacteria and mycetes can't permeate the membrane, this new device may be more hygienic than conventional humidifiers that use water. A more detailed study will be needed to investigate whether bacterial contamination can be completely preventable.

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# Clinical and *in vitro* evaluation of membrane humidifier that does not require addition of water

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It is well known that conventional bubbling humidifiers are capable of producing micro-aerosols contaminated with bacteria. We developed a unique humidifier, named a membrane humidifier, that does not require an external water supply. This new system obtains moisture from room air. We investigated the clinical and *in vitro* evaluation of the membrane humidifier.

Ten patients with chronic pulmonary disease participated in the study. We evaluated the partial pressure of oxygen in arterial blood ($PaO_2$) of 10 patients who used the new device. We conducted an *in vitro* study to determine whether the device could prevent the bacterial contamination of humidified-oxygen. We passed compressed air contaminated with *Pseudomonas aeruginosa* outside the hollow fibres of the membrane humidifier, and the humidified-oxygen passed inside the hollow fibres was sampled into nutrient broth periodically for 10 days. We also compared the relative humidity of oxygen humidified by a membrane humidifier with that of oxygen humidified by a bubbling humidifier.

There was no significant difference between measured $PaO_2$ while breathing oxygen humidified using a membrane humidifier and that while breathing oxygen humidified using a bubbling humidifier. Cultures of the humidified-oxygen passed through the hollow fibres were negative for bacteria. The membrane humidifier could produce good humidification.

The new device appeared to prevent bacterial contamination, and may help to reduce the risk of infection in patients at hospital and home.

RESPIR. MED. (2000) **94**, 71–75 

## Introduction

Dry gas is conventionally humidified for clinical use by a standard bubble water humidifier (1–3). Its disadvantages include difficulty in cleaning the water reservoir and in changing the water. Furthermore, the water reservoir can become contaminated with such hydrophilic species as *Pseudomonas* and *Legionella* (4–6). Such humidifiers have been found to produce micro-aerosols that spread bacterial infection (7). Multiple use of a bubble water humidifier in the hospital can spread pathogens between patients (4,7,8). To reduce the risk of infection, the water reservoir must be cleaned periodically and the water must be changed frequently. We have developed a new humidifier, named a membrane humidifier, whose function does not require the addition of external water for humidification. This new compact device cannot only be used in the hospital, but can also be incorporated in a home oxygen concentrator (9,10). The membrane's surface consists of a dense polymer layer that is free of pinholes. If this new device can prevent bacterial contamination, it will be able to reduce the risk of respiratory infection in both hospital and home. This preliminary study evaluated the membrane humidifier to determine whether bacterial contamination could be prevented. We also evaluated the clinical utility of this new device in a small number of patients.

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## Methods

### PATIENTS

Ten Japanese patients (five men and five women, mean age; 66·6 years) participated in the study after giving their informed consent. They were all hospitalized for the treatment of chronic pulmonary disease with chronic respiratory failure, and were receiving oxygen therapy. Diagnoses were emphysema (three patients), sequelae of tuberculosis (three patients), diffuse panbronchiolitis (two patients), idiopathic interstitial pneumonia (one patient), and interstitial pneumonia with collagen disease (one patient). The clinical condition of each patient was stable. Local Ethical Committees approved the protocol for this study.

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## STRUCTURE AND FUNCTION OF MEMBRANE HUMIDIFIER

The new membrane humidifier is composed of a steel cylinder (length: 210 mm, diameter: 45 mm) containing several hundred hollow fibres made by polyimide resin. The different permeation rate of gases is used to separate water molecules from air. Water vapor can permeate a polyimide membrane of a hollow fibre (UBE membrane, UBE Industries, Ltd., Tokyo, Japan) hundreds of times more readily than either nitrogen or oxygen. The polyimide membrane's surface consists of a dense polymer layer that is free of pinholes. Its pore size is less than $10^{-3}$ $\mu$m (11,12). Compressed air is passed outside the hollow fibres. The compressor can vary the air pressure in the membrane humidifier. As the room air is passed under high pressure through the space around the hollow fibres (outside passage), the water molecules in the air permeate the membrane of the hollow fibres. Dry oxygen from the hospital's oxygen supply is passed through the hollow fibres (inside passage) within the membrane humidifier, and is humidified with water vapour (Fig. 1). This device is compact and can be placed everywhere. A unit of hollow fibres is highly durable. The polyimide membrane of a hollow fibre can be sterilized by alcohol or disinfecting gases. This new system obtains moisture from room air, and the mechanism is original.

## MEASUREMENT

We studied patients from winter to spring. Spirograms (Chestac 55V, Chest IM, Tokyo, Japan) were obtained for each patient prior to the study. The partial pressure of oxygen in arterial blood ($PaO_2$) was measured in the supine position after the patient had breathed each of the followings for 2 h: (a) room air; (b) oxygen via a nasal cannula that was humidified with a membrane humidifier; (c) oxygen via a nasal cannula that was humidified with a conventional bubble water humidifier (Koike Medical Co., Tokyo, Japan). The oxygen from the hospital's supply had an oxygen concentration of nearly 100%. The flow rate through the nasal cannula was 1 l $min^{-1}$ in each patient.

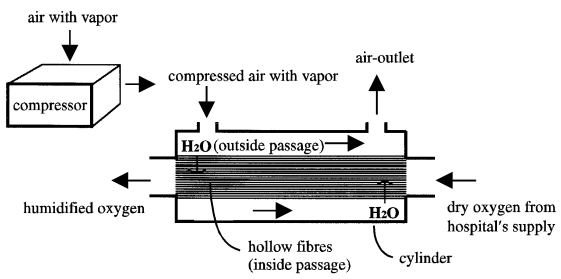


FIG. 1. Structure and function of new membrane humidifier. Compressed air with water vapor is passed through outer passage. Water vapor only permeate the hollow fibres. Dry oxygen from hospital's supply is passed inside hollow fibres, and is humidified with water vapor.

The concentrations of humidified-oxygen were measured directly with an oximeter (LC750, Toray Co., Tokyo, Japan) while using with the membrane humidifier or the conventional bubble water humidifier after the $PaO_2$ had been measured in each patient. We also determined the relative humidity of room air, that of dry oxygen from the hospital's oxygen supply and that of oxygen humidified by a membrane humidifier or a bubble water humidifier. The relative humidity of the dry oxygen delivered from the hospital's oxygen supply and that of the humidified-oxygen from the two different humidifiers were measured with a digital hygrometer (TRH-CA, Shin-ei Co., Tokyo, Japan) after the gases had flowed into a partially opened container (500 ml) for 30 min. The pressure of the compressed air in the membrane humidifier was either 98 kPa (1 kg f $cm^{-2}$) or 196 kPa (2 kg f $cm^{-2}$). The temperatures in the laboratory room were maintained at 20–22°C during the study. During every session, the change of temperature in the laboratory room was maintained within 1°C.

In an *in vitro* study, we evaluated whether the membrane humidifier could prevent bacterial contamination. The outside passage of the hollow fibres in that device was contaminated with 3 ml of fluid containing *Pseudomonas aeruginosa* ($10^8$ $ml^{-1}$). On the first day, the contaminated air from the air-outlet of the outside passage was passed directly for 2 h into 100 ml of nutrient broth (LB Broth, Life Technologies, Inc., ML, USA) as a control, and the humidified-oxygen (1 l $min^{-1}$) that had been passed inside the hollow fibres was sampled into another nutrient broth for 2 h. We also passed the compressed air contaminated with 3-ml of fluid containing $10^8$ $ml^{-1}$ *Pseudomonas aeruginosa* outside the hollow fibres of the membrane humidifier on the second, third, fourth and tenth days of 10 consecutive days, and the humidified-oxygen from the hollow fibres was sampled into the nutrient broth for 2 h. During the 10 days, we did not disinfect the membrane humidifier. Following culture, bacterial identification was performed in the hospital laboratory using quantitative cultures. A sample was taken from 100 ml of the nutrient broth into which either the contaminated compressed air from the outside passage (control) or the humidified-oxygen from the inside passage had been passed. Each sample was diluted with sterile broth to make a 10-fold dilution. We repeated the procedure and made a series of dilution from 10-fold to $10^8$-fold. Each diluted sample was inoculated into a plate of trypto-soy agar (Pearlcore, Eiken Chemical Co., Ltd., Tokyo, Japan) containing 7% rabbit blood and incubated in 5% carbon dioxide and air at 37°C for 24 h. Bacterial growth was identified by genus and species.

## DATA ANALYSIS

Data are reported as mean $\pm$SD. Evaluation of the significance of the difference between two groups utilized the Student's *t*-test. The significance of the results of multiple comparisons was calculated by two-way analysis of variance (ANOVA) using Scheffe's test. Correlation between the relative humidity of room air and that of the

oxygen flow humidified by the membrane humidifier was calculated using single linear regression and Pearson's coefficient (StatFlex, ViewFlex, Tokyo, Japan). A level of $P<0{\cdot}05$ was considered statistically significant.

## Results

The mean percent predicted value of the forced expiratory volume in 1 sec (FEV1) in the 10 patients was $41{\cdot}2\pm15{\cdot}7\%$. The mean $PaO_2$ while the patients breathed room air was $7{\cdot}91\pm1{\cdot}31$ kPa ($59{\cdot}3\pm9{\cdot}8$ mmHg). No significant difference was observed between the $PaO_2$ measured while the patients breathed oxygen that was humidified with the membrane humidifier ($11{\cdot}1\pm1{\cdot}76$ kPa; $83{\cdot}1\pm13{\cdot}2$ mmHg) and with the conventional bubble water humidifier ($11{\cdot}2\pm1{\cdot}87$ kPa; $83{\cdot}9\pm14{\cdot}0$ mmHg). The mean oxygen concentration humidified with the membrane humidifier was $97{\cdot}6\pm1{\cdot}1\%$, and that humidified with the conventional humidifier was $97{\cdot}8\pm1{\cdot}2\%$ when the oxygen from hospital's supply of 100% concentration was passed into the humidifiers. There was no significant difference between them.

The relative humidity of the air in the laboratory room was $37{\cdot}3\pm13{\cdot}9\%$. The relative humidity of the dry oxygen flow delivered by the hospital's oxygen supply was $7{\cdot}1\pm1{\cdot}1\%$ after it had flowed into a partially opened 500 ml container for 30 min. A significant difference was observed between the relative humidity of the oxygen from the membrane humidifier ($82{\cdot}2\pm10{\cdot}7\%$) and that from the conventional bubbling humidifier ($89{\cdot}9\pm2{\cdot}6\%$) ($P<0{\cdot}05$) (Fig. 2). However, when the relative humidity of room air was more than 30% ($n=7$), there was no significant difference between the relative humidity of the oxygen delivered by the membrane device ($88{\cdot}6\pm3{\cdot}8\%$) and that delivered by the conventional bubbling humidifier ($90{\cdot}8\pm2{\cdot}0\%$). A significant linear relationship was observed between the relative humidity of room air and that of the oxygen humidified by the membrane device when the pressure of the compressed air was either 98 kPa (1 kg f $cm^{-2}$) or 196 kPa (2 kg f $cm^{-2}$) (Fig. 3).

The control bacterial cultures showed the presence of $3\times10^5\,ml^{-1}$ *Pseudomonas aeruginosa*, when the compressed air was contaminated by 3-ml fluid containing $10^8\,ml^{-1}$ *Pseudomonas aeruginosa*. However, when the contaminated compressed air was also passed outside the hollow fibres, the cultures of the humidified-oxygen, which had been passed inside the hollow fibres, were negative for bacteria (Table 1).

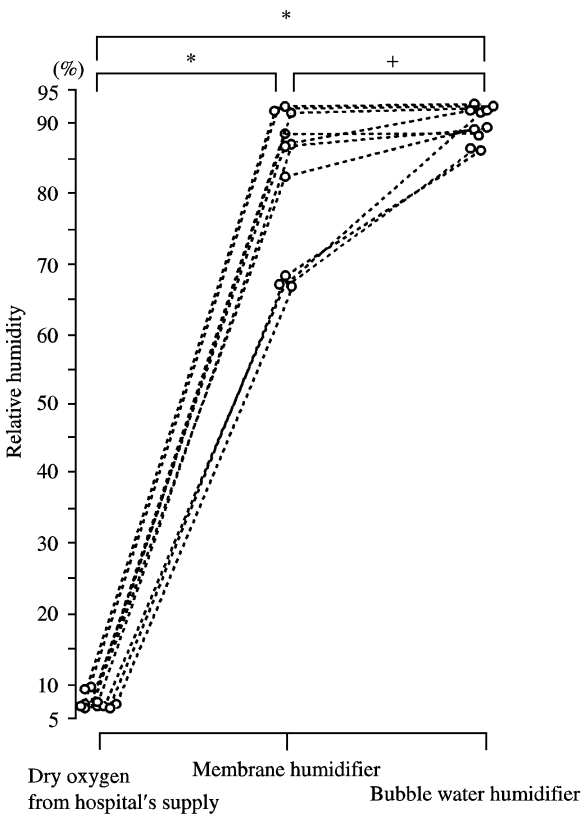


FIG. 2. Relative humidity of dry oxygen from hospital's supply, oxygen humidified by membrane humidifier, and oxygen humidified by bubble water humidifier.
$^*P<0{\cdot}0001$, $^+$: $P<0{\cdot}05$ (Scheffe's test).

## Discussion

Although several reports indicate that routine humidification of oxygen for administration by nasal cannula is not necessary for low flow inhalation (13,14), a reduction in humidity could cause discomfort and adversely affect the respiratory mucosa and ciliary activity (2,3). In many countries, when supplement of dry oxygen is provided by nasal cannula, the oxygen is generally humidified by sterile distilled water using a standard bubble water humidifier. However, sterile distilled water is expensive. We developed a new humidifier, which can humidify dry oxygen without the use of water.

The present study showed that the mean $PaO_2$ in patients was not adversely affected by the new membrane humidifier, because no significant difference was observed between the $PaO_2$ measured while they breathed oxygen from the membrane humidifier or from the conventional bubble water humidifier.

A significant linear relationship was observed between the relative humidity of room air and that of the oxygen humidified by the membrane humidifier. Since this system obtains its water vapour from room air, it appears that its efficiency is diminished when the relative humidity of room air is low (9,10). In previous studies, the pressure of the compressed air in the membrane humidifier was about 98 kPa (1 kg f $cm^{-2}$) (9,10), but the pressure could be variable in this study. The relative humidity of oxygen humidified by the membrane humidifier was increased when the air pressure was increased (Fig. 3).

A significant difference was observed between the relative humidity of the oxygen humidified by the membrane humidifier and that humidified by the conventional

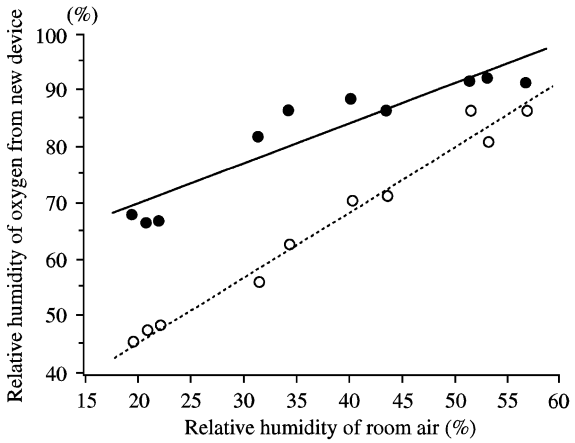


FIG. 3. Single linear regression observed between the relative humidity of room air and that of the oxygen humidified by the new membrane humidifier. ●: significant relationship between the relative humidity of room air and that of oxygen humidified by membrane humidifier when 196 kPa (2 kg f $cm^{-2}$) pressure was added to air ($r^2 = 0{\cdot}87$, $P < 0{\cdot}0001$); ○: significant relationship between the relative humidity of room air and that of oxygen humidified by membrane humidifier when 98 kPa (1 kg $cm^{-2}$) pressure was added to air ($r^2 = 0{\cdot}98$, $P < 0{\cdot}0001$).

bubble water humidifier (Fig. 2), because the mean relative humidity of the oxygen humidified by the new device was 67% when the relative humidity of room air was low (about 19–22%) (Figs. 2 and 3). However, when the relative humidity of room air was above 30%, we found no significant difference between the relative humidity of the oxygen humidified by the membrane humidifier ($88{\cdot}6 \pm 3{\cdot}8\%$) and that humidified by the conventional bubble water humidifier ($90{\cdot}8 \pm 2{\cdot}0\%$). The new membrane humidifier supplied well-moistured nasal oxygen without the need of water. This new device can be incorporated in pressure swing adsorption (PSA) type oxygen concentrator (9,10). Since it eliminates the laborious cleaning of the reservoir and changing of the water, it will be beneficial to the patients in home oxygen therapy.

TABLE 1. Bacterial culture of the air contaminated with 3 ml of fluid containing *Pseudomonas aeruginosa* ($10^8$ $ml^{-1}$) and cultures of the oxygen humidified with a membrane humidifier on the first, second, third, fourth and tenth days of 10 consecutive days

| Day | 1 | 2 | 3 | 4 | 10 |
|---|---|---|---|---|---|
| Culture of contaminated-air as control | (+) | | | | |
| Culture of humidified-oxygen | (−) | (−) | (−) | (−) | (−) |

+: positive, $3 \times 10^5$ $ml^{-1}$ *Pseudomonas aeruginosa*; −: negative, no presence of bacterial growth.

The use of prefilled disposal oxygen humidifier units can reduce the risk of contamination during handling and attachment (5,6). Even though they are sealed, the prefilled disposable oxygen humidifier bottles should be reportedly used within 30 days (6). The new membrane humidifier does not need water for humidification, and the unit of hollow fibres can be durable for about 8 y. In our study, when the compressed air contaminated with *Pseudomonas Aeruginosa* was passed outside the hollow fibres in the new device, cultures of humidified-oxygen that had been passed inside the hollow fibres were negative for bacteria on the first, second, third, fourth and tenth day of 10 consecutive days. If the humidified-oxygen is contaminated with bacteria, the results of cultures from the gas samples will show the positive bacterial growth (4,7). The polyimide membrane used for the hollow fibres in this humidifier has a dense layer of pinhole-free surface. The size of the hole on the surface is considered to be less than $10^{-3}$ $\mu$m (11,12). The size of bacteria is reportedly 0·2–10 $\mu$m, and fungi are generally larger (15). Water vapour that is present in the air dissolves and diffuses into the membrane wall. Since bacteria and fungi cannot permeate the membrane, this new type of membrane humidifier may be less prone to the bacterial contamination than conventional bubbling humidifiers. The new device appears to prevent bacterial contamination of the humidified-oxygen, and its use in the hospital or home setting may reduce the risk of bacterial infection. This device may be used by patients, who need the inhalation of oxygen, in a clean room which no people should enter.

The cost of a unit of the hollow fibres in the membrane humidifier is 30 000 yen. The cost of a compressor used in the membrane humidifier is 50 000 yen. On the other hand, the cost of a conventional bubble water humidifier (Koike medical, Tokyo, Japan) is 20 000 yen. The noise from the compressor is small. When the membrane humidifier is incorporated into PSA type oxygen concentrator, the compressor of the oxygen concentrator can be shared with a membrane humidifier (9), and the cost of the new device is only 30 000 yen.

This new device has many advantages. Detailed, controlled long-term studies are required to delineate further utility of the new membrane humidifier.

## Acknowledgement

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