

遠隔診療の有効性・安全性に関するエビデンスの収集のための 研究方法に関する文献調査

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研究要旨

本研究は、国内外の先行研究から「遠隔診療」に係るエビデンスレベルの高い先行研究文献を調査し、わが国における遠隔診療の有効性・安全性に関するエビデンスの創出を促進するために、遠隔診療に係る研究デザインおよび評価指標ならびに介入条件について文献調査研究を実施した。

Pubmedから抽出した英文論文238編を調査した結果、遠隔診療が慢性疾患や精神疾患領域を対象とした疾病予防・重症化予防に対して有効であることを示した研究が見られたが、遠隔診療が対面診療よりも優れていることを統計的優位に示した研究は少なかった。また、遠隔診療の医療経済評価については患者のQoL値を改善する可能性はあるが経済的に優れているとは言えない結果であった。この理由として公的保険サービスが充足している国では医療の質が高く医療費が安価であるため、対面診療と比べてもあまり変わらない可能性が指摘されていることが明らかとなった。

調査の結果、遠隔診療の効果は受診回数や夜間休日のケア等の治療密度が向上することによる要因が大きいことが示唆された。いっぽう遠隔診療の効果が認められた領域が限定的である理由には、①遠隔診療技術自体の有効性について証明が困難である。②効果が間接的のため、Core Clinical Journal等に掲載される学術論文になりにくい等の理由が考えられる。これらは遠隔診療を「診療技術としての介入行為」、「電子カルテ等の診療基盤」のどちらとして定義するかという論点に深く関連する。

したがって遠隔診療を推進するエビデンスを把握するためには、「診療技術としての介入行為」だけでなく「電子カルテ等の診療基盤」としての評価方法も検討し、遠隔診療に関する学術論文によるエビデンスから学術団体による声明やガイドライン等へ拡大し、諸外国における遠隔診療の動向について網羅的に調査することが望ましい。

A. 研究目的

1. 背景

平成30年度診療報酬改定および平成30年3月30日発行のオンライン診療の適切な実施に関する指針は、遠隔診療のさらなる推進が期待される中、遠隔診療の有効性・安全性に関するエビデンスの必要性は益々高まっている。

しかしながら、遠隔診療の安全性や有効性に関するエビデンスについては十分な整理がされていない。そこで本研究は諸外国における遠隔診療に関する学術論文を中心に、遠隔診療のエビデンスの網羅的調査

を実施することを目的とする。

本研究は、国内外の先行研究から今後どのようなエビデンスの蓄積が必要かを分析し、遠隔診療と親和性の高い診療領域を整理し、どのようなエビデンス蓄積が必要かを分析して遠隔診療普及推進のためのロードマップを策定することである。わが国における遠隔診療の有効性・安全性に関するエビデンスの創出を促進するために、遠隔診療を対象にした先行研究に基づきアウトカム評価指標および介入条件となる遠隔診療行為・技術ならびに研究デザインについて明らかにするために、文献調査研究により網

羅的調査を行う。

2. 研究方法

本研究では既存の有効性・安全性に関するエビデンスの収集状況を調査するために、国内外の先行研究から「遠隔診療」に係るエビデンスレベルの高い文献を網羅的に調査する。

1-1) 検索方法は、pubmedを用いる。

1-2) 検索語はMeSHに基づき、“telemedicine”“telehealth”とする。

1-3) 出版時期は最新5年以内とし、英文雑誌はCore Clinical Journalsに属する学術誌に限定する。

1-4) 論文種別はエビデンスレベルの高いClinical Trial、RCT、Systematic Review・meta-analysis、観察研究を対象とする。

（倫理面への配慮）

本研究は文献研究のため倫理審査対象外である。

C. 研究結果

1) 結果

検索対象となった論文は238編であった。

対象とする診療領域については、慢性期疾患に関する文献は循環器系疾患や呼吸器疾患の領域に多く、急性期疾患に関する文献は脳・神経系疾患、救急系の領域に多く見られた。精神系は、認知症、PTSD、神経心理検査、うつ病、認知行動療法、アルコール依存症、自閉症等幅広い疾患を対象に遠隔診療研究が存在した。また、疾病予防・重症化予防として肥満予防や性感染症予防のほか、服薬指導や薬物中絶によって遠隔診療が用いられる研究事例も見られた。遠隔診療の有効性を示す主な研究報告については以下を例示した。

事例1) 薬剤師の管理による血圧の遠隔モニタリングは通常診療と比べて血圧コントロールを改善するか。（多施設比較試験）

事例2) 脳卒中患者に対する在宅遠隔リハビリテーションの有効性に関する研究

事例3) 英国における遠隔医療技術の費用対効果評価研究

事例4) うつ・不安症に対するcomputerized認知行動療法（CCBT）とInternet support group（ISG）を組み合わせたOnline Collaborative Careの有効性評価（ランダム化比較試験）

事例5) 未熟児網膜症に対する遠隔スクリーニング

事例6) 米国心臓協会による循環器および脳血管疾患に対するTeleHealthの実現に向けた政策提言

事例7) 非急性頭痛に対する遠隔コンサルテーションの長期的有効性・安全性の評価

事例8) 糖尿病治療における遠隔医療の有効性に関するMeta-analysis

D. 考察

本研究では遠隔診療と親和性の高い診療領域を整理し、今後どのような有効性・安全性に関するエビデンス蓄積が必要か分析して、遠隔診療普及推進のためのロードマップを策定するために、既存の有効性・安全性に関するエビデンスの網羅的調査を行った。研究の結果、有効性・安全性に関するエビデンスを一定程度整理することが出来た。

本研究を通じて、遠隔医療の有効性が対面診療よりも優れていることをエビデンスレベルの高い研究（RCT）で示すことができる

領域は現時点では限定的である可能性が示唆された。たとえば糖尿病治療やCOPD等の慢性疾患においては臨床的有効性を示すエビデンスレベルの高い研究成果が見られた。また、注意すべき点として、臨床的有効性について遠隔診療が通常診療よりも劣ってなかったことを示すために、非劣性マージンを設定した研究デザインである「非劣性試験」による文献は該当しなかった。論文の多くでは、「有効性がない結果」から「効果が同等である」という誤った解釈を述べている論文もあり、我が国におけるエビデンスを収集する上でも十分に注意する必要がある。学術論文ではランダム化比較試験等による臨床的有効性についてはCONSORT声明、観察研究についてはSTROBE声明に準拠することが推奨されている。しかしながら本調査に該当する学術論文の多くがこれらの声明に準拠しているとは言えない論文が含まれているため学術論文の信頼性としては十分とは言えない可能性がある。また、遠隔医療に対する医療経済評価については、公的保険サービスが充足している国では医療の質が高く医療費が安価であるため、対面診療と比べてもあまり変わらない可能性が指摘されていることが文献調査から明らかとなった。これはわが国においても当てはまる可能性が高いため、費用対効果評価についてはわが国で行われたエビデンスを蓄積する必要がある。加えてICT技術は進歩が速く関連費用が低減する可能性があるため、最新の研究成果を確認する必要がある。遠隔診療の有効性・安全性が期待される技術や疾患が存在するにもかかわらず、文献調査による検索結果では非該当となった領

域が生じた。その理由には、①遠隔診療技術自体の有効性について証明が困難である。②効果が間接的のため、Core Clinical Journal等に掲載される学術論文になりにくい等の理由が考えられる。これらは遠隔診療を「診療技術としての介入行為」あるいは「電子カルテ等の診療基盤」のどちららとして定義するかという論点に深く関連する。たとえばRemote Sensing Technology等の領域で用いられる医療機器等については、臨床上的効果が間接的で比較対照の設定が難しいために一定以上のエビデンスレベルの研究報告を産み出すことが難しいと考えられる。

遠隔診療を「診療技術としての介入行為」として評価するのであれば、RCTに資する遠隔診療に関するコホートデータベースの整備が求められる。「電子カルテ等の診療基盤」として評価するのであれば、遠隔診療を実施している地域住民等を母集団とした後ろ向き研究デザインが求められる。このように遠隔診療の位置づけによって遠隔診療普及推進のためのロードマップは異なる可能性がある。本調査による諸外国における先行研究から言えることは、遠隔診療を「診療技術としての介入行為」として評価できる疾患領域は限定的でありその効果は通常診療より優れているとは言えないという点である。

今後は遠隔診療の活用が期待される領域や診療ニーズが高い可能性のある診療行為に限定したSystematic ReviewやMeta-analysisを実施する等、遠隔診療技術の有効性に関するエビデンスを蓄積する文献研究が必要であると同時に、「電子カルテ等の診療基盤」としての評価方法を検討するため

に、学術団体が発信している声明やガイドライン等、遠隔診療に関する学術論文以外の資料を含めて検索対象を拡張し、ハンドサーチ等の手法を用いた調査が必要である。

D. 健康危険情報

特になし

E. 参考文献

[1-236]

F. 知的財産権の出願・登録状況

1. 特許取得 無し（非対象）
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 3. その他 無し（非対象）
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