

厚生労働科学研究費補助金(医療機器開発推進研究事業)  
分担研究報告書

レーザー消化管内視鏡治療装置の開発に関する研究

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研究要旨

(株)モリタ製作所、大阪大学、神戸大学で開発してきた試作品に対し、生体ブタを用いた前臨床試験を神戸医療機器開発センター(MEDDEC)において行った。試作品はESDの操作に必要なパワーが十分得られた。本炭酸ガスレーザーシステムはin vivo 生体ブタにおいて、胃粘膜層を切開するが、粘膜層通過後粘膜下層注入材によってレーザー光が吸収され、血管や筋層を傷付けずに、安全に粘膜及び粘膜下層のみを選択的に切除することが出来、より安全な消化器内視鏡治療が実現された。レーザーの生物学的安全性、機械的安全性両方の観点から検討し、さらに装置の改良を進めた。

A. 研究目的

内視鏡的粘膜下層剥離術(ESD)のハイボリュームセンターにおける経験を下に、生体ブタを用いた前臨床試験により、試作品を評価する。

B. 研究方法

(株)モリタ製作所、大阪大学、神戸大学で開発してきた試作品に対し、生体ブタを用いた前臨床試験をMEDDECにおいて行った。レーザーシステムの効果を次の点で評価した。

- ・炭酸ガスレーザー装置の効能
- ・導光ファイバーの効能
- ・ガイド光の効能

(倫理面への配慮)

本課題で行う、生体ブタを用いる前臨床試験に対しては、動物実験委員会で審議、

承認の上、実験動物に対する動物愛護に対して十分配慮した。

C. 研究結果

レーザー装置は、スコープの最大屈曲時にガイド光がやや弱いことが認められたが、十分なレーザーのパワーも有し、操作上に何ら支障が認められなかった。

D. 考察

本研究により開発したレーザー装置および導光ファイバーは、ESD 施術に必要なレーザー出力の要求値を達成できると考える。但し製品化を実現するには、導光ファイバーの透過率のさらなるばらつきを低減し、ファイバー発熱の冷却効率最適化や使用時における導光ファイバーの破断確率の見極めの検討が今後必要である。

## E . 結論

炭酸ガスレーザーによる ESD は、十分な安全性、操作性が得られた。導光ファイバー先端におけるガイド光のパワーの減衰を軽減する改良が必要である。

## F . 健康危険情報

なし。

( 分担研究報告書には記入せずに、総括研究報告書にまとめて記入 )

## G . 研究発表

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- H . 知的財産権の出願・登録状況  
( 予定を含む。 )

1. 特許取得  
なし。
2. 実用新案登録  
なし。
3. その他  
なし。