別添資料５

膿疱性乾癬の疫学およびQOL調査

●汎発性膿疱性乾癬患者の臨床的特徴および成人例，小児例の違いを比較した．37%が再発を経験しており，そのうち80%は重症度が不変・悪化していた．小児膿疱性乾癬の治療では、シクロスポリン内服が増加傾向を示していた．これらの結果をもとに個人調査票を重症度と治療評価が容易な内容に改訂した．また，小児汎発性膿疱性乾癬治療ガイドラインの作成を検討している．

●汎発性膿疱性乾癬患者を対象にSF-36v2を用いたQOL調査を開始した．

これまで回収した症例の解析では，身体機能，日常役割機能(身体)，日常役割機能(精神)，社会生活機能でのQOLが冒されていることが明らかになった．(図)

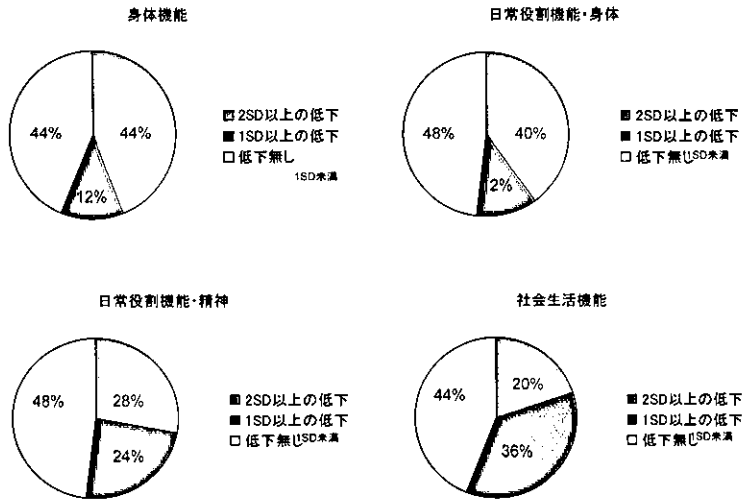


図 SF-36v2による調査で汎発性膿疱性乾癬患者におけるQOLの大きな低下が認められた下位尺度

(難治性疾患克服研究事業)

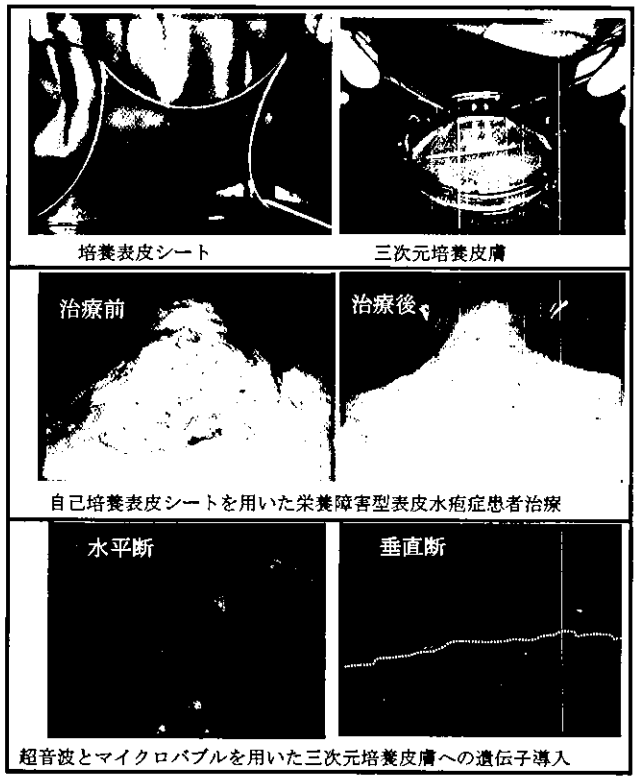
我々は，1995-2003年の日本乾癬学会登録データから汎発性膿疱性乾癬(GPP)症例を抽出し疫学的検討を加えた．GPP再発時の重症度は80%が不変，悪化しており，再発をいかに予防するかが課題と考えられた．小児例（16歳以下）は，GPP全体の11.7%を占め、小児の治療で，シクロスポリンの使用が増加していた．この結果をもとに，重症度と治療評価が容易な形式に個人調査票を改訂した．また小児用治療ガイドラインの作成を検討している．さらにSF-36v2によるQOL調査を開始し，どの健康尺度が冒されるのかを検討している．現在，身体機能，日常役割機能（身体），日常役割機能（精神），社会生活機能の低下が認められており，将来的に，GPPにおけるQOLの特徴を明らかにできる見込みである。

別添資料８

表皮水疱症患者に対する自己培養皮膚を用いた遺伝子再生医療

1. 栄養障害型表皮水疱症患者11例に対し自己培養表皮シート移植の有効性を示し、さらに全国で使用可能な培養表皮シートセンター化システムを構築した。
2. より高度な培養皮膚である三次元培養皮膚移植の有効性を3例の患者で示した。
3. 超音波とマイクロバブルを用いた三次元培養皮膚への新たな遺伝子導入法を開発した。

（難治性疾患克服研究事業）



①培養皮膚よる栄養障害型表皮水疱症の治療法の確立

表皮水疱症患者１１例に対して自己培養表皮シート移植を施行、培養表皮シートをシート状で保存する保存液、保存方法を開発した。この保存法により、培養皮膚センター化方式にて、全国の１０大学に冷凍宅配便で送付し移植に用いた。さらに、三次元培養皮膚を用いたex vivo遺伝子治療の有用性の検討のために、患者３例に対し遺伝子導入前の自己三次元培養皮膚移植を行いその有用性、安全性について検討したところ、生着性が著しく向上し、その有用性が確認できたので、遺伝子治療の可能性が開けた。

②栄養障害型表皮水疱症に対する遺伝子治療

本研究ではⅦ型コラーゲンを高効率かつ安定的に発現させるための発現ベクター開発と、これを用いたⅦ型コラーゲン産生培養皮膚を作製することを目的とし、まず培養皮膚への遺伝子導入法の確立を試みた。アデノウィルスベクター、超音波とマイクロバブルによる遺伝子導入法を開発し、in vitroでの遺伝子発現を確認できたことは重要な成果であると思われる。しかし、その発現は一過性であり、長期間安定した遺伝子発現、表皮基底層における遺伝子発現にはさらなる改良、工夫が必要である。

別添資料９

栄養障害型表皮水疱症の遺伝子治療

（難治性疾患克服研究事業）

1．遺伝子診断による遺伝子治療対象患者の選定（H14－16年）

2．皮膚への遺伝子導入法開発（H14－15年）

3．VII型コラーゲン発現ベクター作成（H15年）

4．骨髄由来末梢血幹細胞を利用した表皮再生法開発（H15－16年）

5．生体組織における長期遺伝子発現法の開発（H15－16年）

6．導入遺伝子産物に対する免疫寛容誘導法開発（H16年）

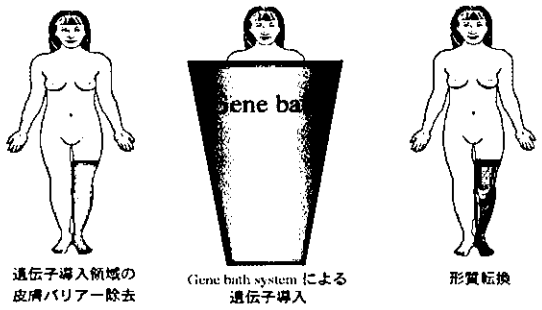


図１．Gene bath system

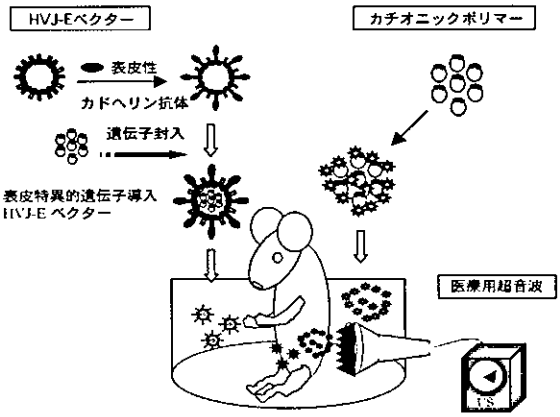


図２．物理的、化学的及び生物学的方法を利用した
gene bathによる遺伝子導入

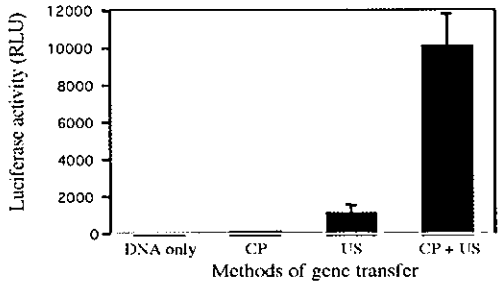


図３．超音波遺伝子導入におけるChemical Peeling の効果

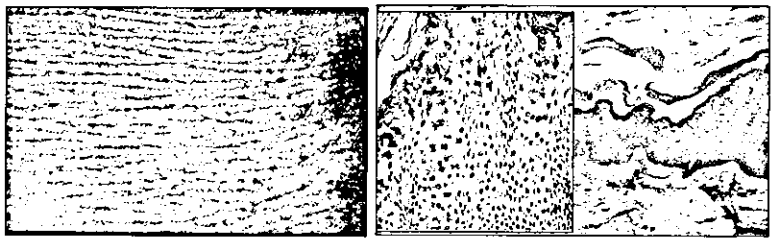
外来診療を通じて遺伝子診断による遺伝子治療対象患者の選定を行う一方、研究面では皮膚への遺伝子導入法開発、VII型コラーゲン発現ベクター作成、長期遺伝子発現法の開発を行った。さらに骨髄由来末梢血幹細胞を利用した表皮再生法と導入遺伝子産物に対する免疫寛容誘導法を開発した。本研究で開発したgene bath systemについて図に示した。治療用遺伝子含有溶液中に患部を浸し（図１）、超音波エネルギーによる細胞膜微小孔形成、カチオニックポリマー修飾による細胞膜への親和性亢進、生物学的方法としてHVJエンベロープベクターの膜融合能をそれぞれ利用することにより（図２）、患部皮膚への低侵襲性・高効率遺伝子導入が可能となった（図３）。

- 表皮水疱症では遺伝子治療が実行できる寸前の状態にあると推察できるので、患者の絶対数が少ないこの疾患の治療研究にはこの研究班の存続が今後ますます求められる。

別添資料10

水疱型先天性魚鱗癬様紅皮症の全国疫学調査

水疱型先天性魚鱗癬様紅皮症の臨床は全身が非常に厚い鱗屑に覆われ、かつ剥がれやすく極めて悲惨な状態でである。



目的：本症の患者数の推定と臨床疫学像を全国規模で初めて明らかにすることを目的とした。

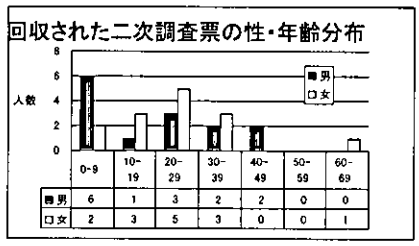
方法：全国の病院から病床規模別に抽出した皮膚科計802科に2003年1月に一次調査を実施し、さらに本症ありと回答のあった施設を二次調査対象とした。

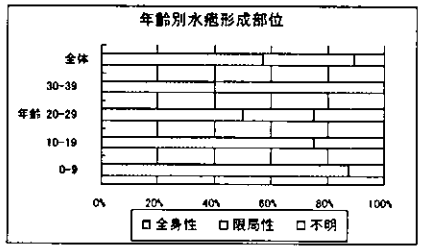
結果：患者数は55人(95%信頼区間35-75人)と推計された。全身の水疱を示す例が57.7%、診断時と比較した現在の病状は不変が42.9%であった。

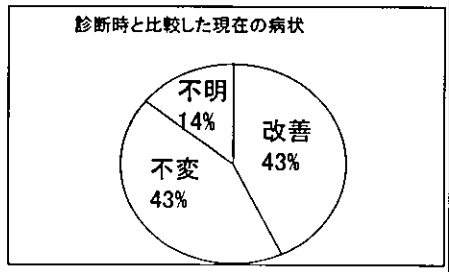
考察：半数以上の患者が全身性の水疱を有し、診断治療後も症状の改善を見ていないことが明らかになった。本研究事業によって本症の病態解明と治療法を確立することが必要と考えられた。

〈 難治性疾患克服研究事業 〉

二次調査結果







水疱型先天性魚鱗癬様紅皮症の原因遺伝子（ケラチン1 または10）は明らかにされたが、病態、治療法のみならず本邦における患者数さえも明らかではない。皮膚科計802科に2002年1年間の受療患者を対象とし（507科、回収率は63.2%）、二次調査票から2002年1年間に本疾患で全国の病院を受療した患者数は55人(95%信頼区間35-75人)と推計された。適正二次調査票は28例で、男女各14例、年齢は2ー65歳、地域集積性は認められず、家族歴3例（10.7%）、全身性皮疹27例(96.4%)、紅皮症19例(67.9%)、全身の水疱15例(57.7%)、手指拘扼3例(10.7%)、姿勢異常１例(3.6%)、歩行障害４例(14.3%)等であった。診断時と比較した現在の病状は改善と不変が同割合(42.9%)であった。以上から半数以上の患者が全身性の水疱を有し、診断治療後も症状の改善を見ていないことが明らかになった。

•病因としてはケラチン線維の異常によって層板顆粒の分泌過程が2次的に障害されタンパク分解酵素の供給が不十分となり、角層細胞間の接着構造の分解過程が遅延すると推定された。かつ変異ケラチン凝集塊を持つ角化細胞では、TNF-a の産生が亢進、20Sプロテアソームの機能抑制があった。これらは臨床像形成に関与している可能性がある。

•本研究事業によって本症の病態解明と治療法を確立することが必要と考えられた。

Ⅲ　研究成果の刊行に関する一覧表

1．雑誌

著者名	論文題目	雑誌名	巻：頁、西暦年号
Gu LH, Ichiki Y, Sato M, Kitajima Y	A novel nonsense mutation at E106 of the 2B rod domain of keratin 14 cases dominant epidermolysis bullosa simplex	**J Dermatol**	29 : 136-145, 2002
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South AP, Ashton GHS, Willoughby C, Ellis IH, Bleck O, Hamada T, Mannion G, Wessagowit V, Hashimoto T, Eady RAJ, McGrath JA	EEC (ectodactyly, ectodermal dysplasia) syndrome: heterozygous mutation in the p63 gene (R279H) and DNA-based antenatal diagnosis	**Br J Dermatol**	146 : 216-220, 2002
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